

US3372089 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:12:37

All time stamps listed in this document are displayed in GMT

US3372089

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

[Participant ID](#)

US3372089

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

US3372089

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

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) 15 Feb 2021 17:24:59

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Date of Birth (MMM yyyy)	(b) (6) 1946
Age	74
Age Units	YEARS
Age (Derived)	74
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) 15 Feb 2021 17:24:59

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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 checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:24:59

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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) 15 Feb 2021 17:24:59

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Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Condition	PERIPHERAL NEUROPATHY
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Condition	GENERALIZED OSTEOARTHRITIS
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) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Condition	HERNIATED DISC CERVICAL SPINE
Start date (dd MMM yyyy)	UN UNK 1989
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 UNK 1989
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	JAN 1989
Stop Year (derived)	1989

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Condition	CERVICAL FUSION
Start date (dd MMM yyyy)	UN UNK 1995
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 UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Condition	OSTEOARTHRITIS RIGHT SHOULDER
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Condition	ARTHROSCOPIC DEBRIDEMENT RIGHT SHOULDER
Start date (dd MMM yyyy)	UN UNK 2012
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 UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Condition	TORN CARTILAGE RIGHT KNEE
Start date (dd MMM yyyy)	UN UNK 1968
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 UNK 1968
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1968
Start Year (derived)	1968
Stop Month and Year (derived)	JAN 1968
Stop Year (derived)	1968

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Condition	ARTHROPLASTY RIGHT KNEE
Start date (dd MMM yyyy)	UN UNK 1968
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 UNK 1968
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1968
Start Year (derived)	1968
Stop Month and Year (derived)	JAN 1968
Stop Year (derived)	1968

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 1994
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 UNK 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1994
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 UNK 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Condition	BILATERAL UPPER EXTREMITY DERMATOSES
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:40 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 14:40
Height (<i>xxx.x</i>)	175.5 cm
Weight (<i>xxx.x</i>)	98.1 kg
BMI (<i>xxx.x</i>)	31.85039 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:24:59

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:24:59

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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 ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:24:59

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	(b) (6) APARTMENT, WHERE THERE IS OTHER WORKERS.

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

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) 15 Feb 2021 17:24:59

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

What was the participant's randomization number? 185670

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

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) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

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)	14:40 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 14:40
Temperature (xxx.x)	36 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	16:45 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 16:45
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

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) 16:11 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 16:11

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) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 AUG 2020
Collection time (00:00-23:59)	15:18 (24 HR)
Collection date and time (derived)	11 AUG 2020 15:18

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

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	15:17	11 AUG 2020 15:17
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

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 17:12:37

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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 16:46

PC Open Date & Time

11 AUG 2020 16:31

PC Close Date & Time

11 AUG 2020 19:01

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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 97.2 °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):

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

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

PC Time Stamp 12 AUG 2020 10:40

PC Open Date & Time 11 AUG 2020 19:56

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 17:12:37

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	12 AUG 2020 17:51
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 16:23

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	14 AUG 2020 17:20
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 16:20

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

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

98.3 °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

16 AUG 2020 16:12

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

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

98.2 °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

17 AUG 2020 16:52

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 16:47

PC Open Date & Time

11 AUG 2020 16:31

PC Close Date & Time

11 AUG 2020 19:01

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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

12 AUG 2020 10:36

PC Open Date & Time

11 AUG 2020 19:56

PC Close Date & Time

12 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

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 17:51

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

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 16:24

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

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 17:21

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

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 16:21

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

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 16:12

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

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 16:52

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 16:48
PC Open Date & Time	11 AUG 2020 16:31
PC Close Date & Time	11 AUG 2020 19:01

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 10:38
PC Open Date & Time	11 AUG 2020 19:56
PC Close Date & Time	12 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

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

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EAB) (1725)

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 17:52
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

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

56 of 2912

EAB) (1725)

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 16:25
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

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

58 of 2912

EAB) (1725)

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 17:21
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

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 ☒

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 16:22
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

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)

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

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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US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 16:53
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:12:37

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 15:53

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:12:37

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 12:01

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:12:37

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

20 AUG 2020 16:36

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:12:37

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

21 AUG 2020 17:44

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:12:37

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

22 AUG 2020 12:05

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:12:37

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

23 AUG 2020 12:25

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:12:37

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

24 AUG 2020 16:53

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:12:37

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

25 AUG 2020 12:52

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:12:37

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

26 AUG 2020 12:07

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:12:37

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

27 AUG 2020 12:28

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 17:12:37

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

28 AUG 2020 12:02

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 17:12:37

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

29 AUG 2020 15:31

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 17:12:37

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

30 AUG 2020 12:08

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 17:12:37

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

31 AUG 2020 14:17

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 17:12:37

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

01 SEP 2020 16:57

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 17:12:37

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

02 SEP 2020 12:05

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 17:12:37

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

03 SEP 2020 16:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 17:12:37

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

04 SEP 2020 12:20

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 17:12:37

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

05 SEP 2020 12:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 17:12:37

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

07 SEP 2020 04:51

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 17:12:37

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

07 SEP 2020 12:45

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 17:12:37

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

08 SEP 2020 16:39

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 17:12:37

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

09 SEP 2020 12:01

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:12:37

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 15:53

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:12:37

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 12:01
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PC Open Date & Time	19 AUG 2020 12:00
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PC Close Date & Time	20 AUG 2020 11:59
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US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:12:37

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 20 AUG 2020 16:36

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:12:37

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 21 AUG 2020 17:45

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 12

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 22 AUG 2020 12:05

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:12:37

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 23 AUG 2020 12:25

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 14

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 AUG 2020 16:53

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:12:37

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 25 AUG 2020 12:52

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 16

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 26 AUG 2020 12:07

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:12:37

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 27 AUG 2020 12:28

PC Open Date & Time 27 AUG 2020 12:00

PC Close Date & Time 28 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 18

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 28 AUG 2020 12:02

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 19

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 29 AUG 2020 15:31

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 17:12:37

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 30 AUG 2020 12:08

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 17:12:37

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 31 AUG 2020 14:18

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 17:12:37

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

01 SEP 2020 16:57

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 17:12:37

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

02 SEP 2020 12:05

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 24

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 SEP 2020 16:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 17:12:37

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

04 SEP 2020 12:20

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 17:12:37

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 05 SEP 2020 12:01

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 17:12:37

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 07 SEP 2020 04:52

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 28

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 SEP 2020 12:45

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 17:12:37

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 08 SEP 2020 16:39

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 17:12:37

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 09 SEP 2020 12:01

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:12:37

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 15:53

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:12:37

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 12:01

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:12:37

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 20 AUG 2020 16:36

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:12:37

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 21 AUG 2020 17:45

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:12:37

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 12:05

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:12:37

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 12:25

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:12:37

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 16:53

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:12:37

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 12:53

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:12:37

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 12:07

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:12:37

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 12:28

PC Open Date & Time 27 AUG 2020 12:00

PC Close Date & Time 28 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:12:37

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 12:02

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:12:37

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 15:31

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:12:37

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 12:08

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 17:12:37

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 14:18

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 17:12:37

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 16:57

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 17:12:37

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 12:06

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 17:12:37

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 16:04

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 17:12:37

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 12:21

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 17:12:37

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 12:01

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 17:12:37

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 07 SEP 2020 04:52

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 17:12:37

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 12:45

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 17:12:37

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 16:39

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 17:12:37

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 09 SEP 2020 12:01

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 AUG 2020 15:53
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 AUG 2020 12:02
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	20 AUG 2020 16:37
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 AUG 2020 17:45
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 AUG 2020 12:05
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 AUG 2020 12:26
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 AUG 2020 16:53
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 AUG 2020 12:53
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 AUG 2020 12:02
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 AUG 2020 15:31
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 AUG 2020 12:09
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 AUG 2020 14:18
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 SEP 2020 16:57
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 SEP 2020 12:06
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 SEP 2020 16:04
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 SEP 2020 12:21
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 SEP 2020 12:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 SEP 2020 04:52
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 SEP 2020 12:45
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	08 SEP 2020 16:39
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	08 SEP 2020 16:39
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	08 SEP 2020 16:39
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	09 SEP 2020 12:01
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3372089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3372089

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

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)	09 SEP 2020
Time of assessment (00:00-23:59)	14:26 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 14:26
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)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

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)	09 SEP 2020
Time of assessment (00:00-23:59)	15:59 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 15:59
Temperature (xxx.x)	36.3 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)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3372089

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 2020

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

US3372089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 15:19 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 15:19

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

US3372089

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 SEP 2020
Collection time (00:00-23:59)	14:45 (24 HR)
Collection date and time (derived)	09 SEP 2020 14:45

US3372089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Collection date (dd MMM yyyy)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:42	09 SEP 2020 14:42
Nasopharyngeal Swab 2	No		

US3372089

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

09 SEP 2020 16:00

PC Open Date & Time

09 SEP 2020 15:39

PC Close Date & Time

09 SEP 2020 18:09

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	09 SEP 2020 19:05
PC Open Date & Time	09 SEP 2020 19:04
PC Close Date & Time	10 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

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

97.5 °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

10 SEP 2020 18:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

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

95.6 °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 19:52

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

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

98.4 °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

12 SEP 2020 15:31

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

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

98.3 °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

13 SEP 2020 16:41

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

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

98.9 °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

14 SEP 2020 16:43

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 15:14

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 16:00

PC Open Date & Time

09 SEP 2020 15:39

PC Close Date & Time

09 SEP 2020 18:09

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 19:06

PC Open Date & Time

09 SEP 2020 19:04

PC Close Date & Time

10 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 18:21

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 19:52

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 15:31

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 16:39

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 16:44

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 15:15

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 16:01
PC Open Date & Time	09 SEP 2020 15:39
PC Close Date & Time	09 SEP 2020 18:09

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 19:07
PC Open Date & Time	09 SEP 2020 19:04
PC Close Date & Time	10 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

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 ☒

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 18:21
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

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

196 of 2912

EAB) (1725)

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 19:53
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

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

198 of 2912

EAB) (1725)

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 15:32
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

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

200 of 2912

EAB) (1725)

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 16:39
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

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 ☒

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 16:44
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

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 ☒

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3372089

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

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

If Contact Not Made, please provide Comments

US3372089

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372089

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

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) _____

US3372089

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

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.

US3372089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 OCT 2020
Collection time (00:00-23:59)	10:36 (24 HR)
Collection date and time (derived)	06 OCT 2020 10:36

US3372089

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 OCT 2020 16:09:40
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 03:49:16

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 OCT 2020 03:06:08

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 02:03:29
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

22 NOV 2020 08:14:13

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 12:32:19
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 06:49:48

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 16:05:34
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

17 DEC 2020 01:52:46

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 13:03:46

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

31 DEC 2020 00:18:23

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

07 JAN 2021 08:28:55

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 05:37:46

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 173

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

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

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

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

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

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

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 FEB 2021 12:35:07
Patient Cloud Open Date & Time	18 FEB 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
240 of 2912	

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 FEB 2021 04:21:12
Patient Cloud Open Date & Time	25 FEB 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
242 of 2912	

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 00:05:07

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 09:26:58

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 08:52:03

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 02:12:47

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 00:02:51
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

08 APR 2021 06:33:34

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

15 APR 2021 01:04:08

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 03:17:43

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 02:54:43

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Date and time of submission	
Patient Cloud Open Date & Time	13 MAY 2021 00:01
Patient Cloud Close Date & Time	17 MAY 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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"/>

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 299

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUN 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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"/>

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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"/>

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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"/>

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2021 00:01
Patient Cloud Close Date & Time	15 NOV 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2021 00:01
Patient Cloud Close Date & Time	22 NOV 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 481

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°F/38°C)

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 <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"/>

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 JUN 2022 00:01
Patient Cloud Close Date & Time	13 JUN 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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"/>

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3372089

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:12:37

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		04 MAR 2021 00:05:29

US3372089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372089

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372089

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372089

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 13:16:02

Generated On: 09 Jun 2021 17:12:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 13:16:02

Generated On: 09 Jun 2021 17:12:37

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) _____

US3372089

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 16:27:41

Generated On: 09 Jun 2021 17:12:37

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.

US3372089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 13:16:02

Generated On: 09 Jun 2021 17:12:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 MAR 2021
Collection time (00:00-23:59)	09:19 (24 HR)
Collection date and time (derived)	08 MAR 2021 09:19

US3372089

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 16:27:41

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 18:52:49

Generated On: 09 Jun 2021 17:12:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372089

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:52:49

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372089

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:12:37

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"/>

US3372089

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:12:37

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3372089

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3372089

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 13:16:02

Generated On: 09 Jun 2021 17:12:37

Date of updated informed consent (<i>dd MMM yyyy</i>)	18 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 (<i>dd MMM yyyy</i>)	18 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

US3372089

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3372089

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

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)	18 JAN 2021
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 10:40
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3372089

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

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)	18 JAN 2021
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 11:38
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3372089

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

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.

US3372089

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

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) 18 JAN 2021

What was the treatment time? (00:00-23:59) 11:03 (24 HR)

Treatment Date and Time (derived) 18 JAN 2021 11:03

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

US3372089

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

10:12 (24 HR)

Collection date and time (derived)

18 JAN 2021 10:12

US3372089

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	18 JAN 2021
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Collection time (00:00 - 23:59)	10:11
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Collection Date and Time (derived)	18 JAN 2021 10:11
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US3372089

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372089

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:24:59

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3372089

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:40:23

Generated On: 09 Jun 2021 17:12:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 19:40:23

Generated On: 09 Jun 2021 17:12:37

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)	15 FEB 2021
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 10:20
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 19:40:23

Generated On: 09 Jun 2021 17:12:37

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)	15 FEB 2021
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 11:20
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input checked="" type="checkbox"/>
If Other, specify	FOREHEAD
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3372089

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:40:23

Generated On: 09 Jun 2021 17:12:37

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.

US3372089

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 19:40:23

Generated On: 09 Jun 2021 17:12:37

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) 15 FEB 2021

What was the treatment time? (00:00-23:59) 10:50 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 10:50

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

US3372089

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:30:39

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 21:49:42

Generated On: 09 Jun 2021 17:12:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372089

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 21:49:42

Generated On: 09 Jun 2021 17:12:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372089

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 16:27:41

Generated On: 09 Jun 2021 17:12:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Mar 2021 16:27:41

Generated On: 09 Jun 2021 17:12:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	12:29 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 12:29
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372089

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 16:27:41

Generated On: 09 Jun 2021 17:12:37

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.

US3372089

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Mar 2021 16:27:41

Generated On: 09 Jun 2021 17:12:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	12:36 (24 HR)
Collection date and time (derived)	15 MAR 2021 12:36

US3372089

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Mar 2021 16:27:41

Generated On: 09 Jun 2021 17:12:37

AEID

Adverse event

BASAL CELL CARCINOMA -
RIGHT SHOULDER LATERAL.

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

8 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Mar 2021 16:27:41

Generated On: 09 Jun 2021 17:12:37

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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Mar 2021 16:27:41

Generated On: 09 Jun 2021 17:12:37

AEID

Adverse event

SQUAMOUS CELL CARCINOMA
- LEFT UPPER ARM LATERAL.

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

8 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Mar 2021 16:27:41

Generated On: 09 Jun 2021 17:12:37

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Mar 2021 16:27:41

Generated On: 09 Jun 2021 17:12:37

AEID	USA-US056-2021-MRNA-1273-P30 1000010
Adverse event	MUSCLE WEAKNESS LOWER EXTREMITIES
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)	16 FEB 2021
Start time (00:00-23:59)	02:50 (24 HR)
AE start date and time (derived)	16 FEB 2021 02:50
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 FEB 2021
End time (00:00-23:59)	11:57 (24 HR)
AE End Date and Time (derived)	17 FEB 2021 11:57
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	17 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" 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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Form: Adverse Events (3)

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THIS WAS REPORTED ON
16-FEB-2021 VIA PAPER
SUBMISSION DUE TO EDC
BEING DOWN.

SUBJECT CONTACTED THE SITE
REGARDING BEING IN THE ER
DUE TO HAVING SEVERE
MUSCLE WEAKNESS OF THE
LOWER EXTREMITIES AND
UNABLE TO STAND, FEVER >
102, AND URINARY RETENTION.

SUBJECT RECEIVED THEIR
SECOND DOSE OF MRNA 1273
ON 15-FEB-2021.
SUBJECTS FIRST DOSE WAS ON
18-JAN-2021.

PI, M. BARON MD SPOKE WITH
THE ER PHYSICIAN ATTENDING
TO THE SUBJECT. SUBJECT IS
PRESENTLY AFEBRILE,
URINARY RETENTION
RESOLVED BUT STILL HAS
WEAKNESS IN BOTH LOWER
EXTREMITIES AND DIFFICULTY
WALKING. SUBJECT IS BEING
ADMITTED FOR OBSERVATION.

AT PRESENT TIME NO FURTHER
INFORMATION IS AVAILABLE.

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Mar 2021 16:27:41

Generated On: 09 Jun 2021 17:12:37

AEID	
Adverse event	PYREXIA
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)	16 FEB 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)	16 FEB 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 type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Form: Adverse Events (4)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Mar 2021 16:27:41

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AEID

Adverse event

URINARY RETENTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Mar 2021 16:27:41

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 17:24:58

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 20:01:49

Generated On: 09 Jun 2021 17:12:37

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 20:01:49

Generated On: 09 Jun 2021 17:12:37

	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 2017	
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) 17 Feb 2021 20:01:49

Generated On: 09 Jun 2021 17:12:37

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication PERIPHERAL NEUROPATHY

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) 17 Feb 2021 20:01:49

Generated On: 09 Jun 2021 17:12:37

	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 2019	
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) 17 Feb 2021 20:01:49

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Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED ARTHRITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 17 Feb 2021 20:01:49

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	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 2018	
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)	2	
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) 17 Feb 2021 20:01:49

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Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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	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)	UN AUG 2018	
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) 17 Feb 2021 20:01:49

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Name of Medication PNEUMONIA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PNEUMONIA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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	Intraocular	<input type="radio"/>
	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)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN UNK 2018
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 (6)

Data signed: (b) (4) 17 Feb 2021 20:01:49

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 17 Feb 2021 20:01:49

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	Intraocular	<input type="radio"/>
	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)	UN SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN SEP 2019
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 17 Feb 2021 20:01:49

Generated On: 09 Jun 2021 17:12:37

Name of Medication HYDROCORTISONE CREAM
2.5%

Prophylaxis Yes ☐
No ☒

Indication BILATERAL UPPER EXTREMITY
DERMATOSIS

Dose per administration 1

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

If dose unit is Other, specify DAB

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 17 Feb 2021 20:01:49

Generated On: 09 Jun 2021 17:12:37

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
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"/>

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 17 Feb 2021 20:01:49

Generated On: 09 Jun 2021 17:12:37

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

476 of 2912

EAB) (1725)

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 17 Feb 2021 20:01:49

Generated On: 09 Jun 2021 17:12:37

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 2020
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"/>

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 17 Feb 2021 20:01:49

Generated On: 09 Jun 2021 17:12:37

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PYREXIA

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 ☐

PRODUCTION RELEASE (v12.003

478 of 2912

EAB) (1725)

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 17 Feb 2021 20:01:49

Generated On: 09 Jun 2021 17:12:37

	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)	16 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Feb 2021 17:24:58

Generated On: 09 Jun 2021 17:12:37

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 AUG 2020	BIOPSY BASAL CELL CARCINOMA - RIGHT SHOULDER LATERAL	Adverse Event	
18 AUG 2020	BIOPSY SQUAMOUS CELL CARCINOMA - LEFT POSTERIOR UPPER ARM	Adverse Event	
8 SEP 2020	BASAL CELL CARCINOMA EXCISION - RIGHT SHOULDER LATERAL.	Adverse Event	
8 SEP 2020	EXCISION SQUAMOUS CELL CARCINOMA - LEFT POSTERIOR UPPER ARM.	Adverse Event	

US3372089

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:12:37

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

US3372089

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:12:37

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 ☐

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 17 Mar 2021 17:49:08

Generated On: 09 Jun 2021 17:12:37

SAEID	USA-US056-2021-MRNA-1273-P301000010
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	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 17 Mar 2021 17:49:08

Generated On: 09 Jun 2021 17:12:37

SAEID	USA-US056-2021-MRNA-1273-P301000010
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	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	17/FEB/2021 13:40
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

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 17 Mar 2021 17:49:08

Generated On: 09 Jun 2021 17:12:37

SAEID	USA-US056-2021-MRNA-1273-P301000010
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	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	25/FEB/2021 13:31
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

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 17 Mar 2021 17:49:08

Generated On: 09 Jun 2021 17:12:37

SAEID	USA-US056-2021-MRNA-1273-P301000010
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	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	17/MAR/2021 10:31
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

US3372089 (Prod: Palm Beach Research Center)

US3372089

Form: Participant Creation

Generated On: 09 Jun 2021 17:12:37

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'US3372089'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:09:29

US3372089

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:15:25

US3372089

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:09:30

US3372089

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Clinic (Clinic)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:15:25

US3372089

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'SCRN'	System	11 Aug 2020 18:15:25

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered (b) (6) 1946'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:09:31

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '74'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:30

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'YEARS'	System	11 Aug 2020 18:16:30

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '74'	System	11 Aug 2020 18:16:47

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Male (M)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:30

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:30

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'I'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:30

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:30

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:30

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:30

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:30

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:30

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:30

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:30

US3372089

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:37

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:30

US3372089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:37

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '11 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:47

US3372089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Aug 2020'	System	11 Aug 2020 18:16:47

US3372089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '2020'	System	11 Aug 2020 18:16:47

US3372089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:37

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Amendment 1 (1)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:47

US3372089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:47

US3372089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:37

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:47

US3372089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:37

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:47

US3372089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:37

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:47

US3372089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:37

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:09:30

US3372089

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:37

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'I'	System	11 Aug 2020 18:16:53

US3372089

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:16:53

US3372089

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:12:37

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Aug 2020 19:16:46

US3372089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:48:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:48:34
Data point term sent to Coder	System	29 Sep 2020 15:47:11
User entered 'hyperlipidemia'	Peter Jacob (b) (4)	29 Sep 2020 15:46:43

US3372089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 2017'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:46:43

US3372089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:46:43

US3372089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:46:43

US3372089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:46:43

US3372089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:46:43

US3372089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 2017'	System	29 Sep 2020 15:46:43

US3372089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '2017'	System	29 Sep 2020 15:46:43

US3372089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered empty.	System	29 Sep 2020 15:46:43

US3372089

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered empty.	System	29 Sep 2020 15:46:43

US3372089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
Query 'Per DM CLR: Please verify the type of the PERIPHERAL NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:11:13
User opened query 'Per DM CLR: Please verify the type of the PERIPHERAL NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 17:37:10
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:48:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:48:35
Data point term sent to Coder	System	29 Sep 2020 15:47:12
User entered 'peripheral neuropathy'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:46:57

US3372089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:46:57

US3372089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:46:57

US3372089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:46:57

US3372089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:46:57

US3372089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:46:57

US3372089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:37

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 2019'	System	29 Sep 2020 15:46:57

US3372089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '2019'	System	29 Sep 2020 15:46:57

US3372089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered empty.	System	29 Sep 2020 15:46:57

US3372089

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered empty.	System	29 Sep 2020 15:46:57

US3372089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:48:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:48:36
Data point term sent to Coder	System	29 Sep 2020 15:47:11
User entered 'gastroesophageal reflux disease'	Peter Jacob (b) (4)	29 Sep 2020 15:47:09

US3372089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:09

US3372089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:09

US3372089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:09

US3372089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 15:47:09

US3372089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	Peter Jacob (b) (4)	29 Sep 2020 15:47:09

US3372089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:37

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 2018'	System	29 Sep 2020 15:47:09

US3372089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '2018'	System	29 Sep 2020 15:47:09

US3372089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered empty.	System	29 Sep 2020 15:47:09

US3372089

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered empty.	System	29 Sep 2020 15:47:09

US3372089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:49:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:49:39
Data point term sent to Coder	System	29 Sep 2020 15:48:13
User entered 'generalized osteoarthritis'	Peter Jacob (b) (4)	29 Sep 2020 15:47:21

US3372089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 1990'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:21

US3372089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:21

US3372089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:21

US3372089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:21

US3372089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:21

US3372089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 1990'	System	29 Sep 2020 15:47:21

US3372089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '1990'	System	29 Sep 2020 15:47:21

US3372089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered empty.	System	29 Sep 2020 15:47:21

US3372089

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered empty.	System	29 Sep 2020 15:47:21

US3372089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please confirm since a procedure for this condition (MH# 06) was reported (UN UNK 1995-UN UNK 1995). Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 11:52:16
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please confirm since a procedure for this condition (MH# 06) was reported (UN UNK 1995-UN UNK 1995). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 17:37:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Cervical disc herniation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:49:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:49:40
Data point term sent to Coder	System	29 Sep 2020 15:48:13
User entered 'herniated disc cervical spine'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:47:40

US3372089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 1989'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:40

US3372089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	Peter Jacob (b) (4)	29 Sep 2020 15:47:40

US3372089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:40

US3372089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 1989'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:40

US3372089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:40

US3372089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 1989'	System	29 Sep 2020 15:47:40

US3372089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '1989'	System	29 Sep 2020 15:47:40

US3372089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 1989'	System	29 Sep 2020 15:47:40

US3372089

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '1989'	System	29 Sep 2020 15:47:40

US3372089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion cervical spine - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:49:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:49:39
Data point term sent to Coder	System	29 Sep 2020 15:48:14
User entered 'cervical fusion'	Peter Jacob (b) (4)	29 Sep 2020 15:47:59

US3372089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:59

US3372089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:59

US3372089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:47:59

US3372089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:47:59

US3372089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:47:59

US3372089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 1995'	System	29 Sep 2020 15:47:59

US3372089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '1995'	System	29 Sep 2020 15:47:59

US3372089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 1995'	System	29 Sep 2020 15:47:59

US3372089

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '1995'	System	29 Sep 2020 15:47:59

US3372089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User closed query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 08) was reported (UN UNK 2012-UN UNK 2012). Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 12:52:23
Query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 08) was reported (UN UNK 2012-UN UNK 2012). Update eCRF as appropriate. ' answered with 'Confirmed ongoing even after procedure' (Site from DM).	Mary Sergalis (b) (4)	05 Nov 2020 15:04:12
User opened query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 08) was reported (UN UNK 2012-UN UNK 2012). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 17:37:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Shoulder osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:49:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:49:40
Data point term sent to Coder	System	29 Sep 2020 15:48:14
User entered 'osteoarthritis right shoulder'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:48:10

US3372089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 2005'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:48:10

US3372089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	Peter Jacob (b) (4)	29 Sep 2020 15:48:10

US3372089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:48:10

US3372089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 15:48:10

US3372089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	Peter Jacob (b) (4)	29 Sep 2020 15:48:10

US3372089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 2005'	System	29 Sep 2020 15:48:10

US3372089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '2005'	System	29 Sep 2020 15:48:10

US3372089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered empty.	System	29 Sep 2020 15:48:10

US3372089

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered empty.	System	29 Sep 2020 15:48:10

US3372089

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 17:09:29
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 17:38:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Joint debridement, LLT: Joint debridement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 21:19:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 21:19:28
Data point term sent to Coder	System	29 Sep 2020 15:49:15
User entered 'arthroscopic debridement right shoulder'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:48:30

US3372089

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 2012'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:48:30

US3372089

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	Peter Jacob (b) (4)	29 Sep 2020 15:48:30

US3372089

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:48:30

US3372089

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 2012'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:48:30

US3372089

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:48:30

US3372089

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 2012'	System	29 Sep 2020 15:48:30

US3372089

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '2012'	System	29 Sep 2020 15:48:30

US3372089

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 2012'	System	29 Sep 2020 15:48:30

US3372089

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '2012'	System	29 Sep 2020 15:48:30

US3372089

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Cartilage injury, LLT: Cartilage tear in knee - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:49:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:49:41
Data point term sent to Coder	System	29 Sep 2020 15:49:16
User entered 'torn cartilage right knee'	Peter Jacob (b) (4)	29 Sep 2020 15:48:56

US3372089

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 1968'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:48:56

US3372089

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:48:56

US3372089

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:48:56

US3372089

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 1968'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:48:56

US3372089

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	Peter Jacob (b) (4)	29 Sep 2020 15:48:56

US3372089

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 1968'	System	29 Sep 2020 15:48:56

US3372089

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '1968'	System	29 Sep 2020 15:48:56

US3372089

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 1968'	System	29 Sep 2020 15:48:56

US3372089

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '1968'	System	29 Sep 2020 15:48:56

US3372089

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Arthroplasty of knee - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:49:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:49:41
Data point term sent to Coder	System	29 Sep 2020 15:49:18
User entered 'arthroplasty right knee'	Peter Jacob (b) (4)	29 Sep 2020 15:49:14

US3372089

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 1968'	Peter Jacob (b) (4)	29 Sep 2020 15:49:14

US3372089

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	Peter Jacob (b) (4)	29 Sep 2020 15:49:14

US3372089

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:49:14

US3372089

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 1968'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:49:14

US3372089

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	Peter Jacob (b) (4)	29 Sep 2020 15:49:14

US3372089

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 1968'	System	29 Sep 2020 15:49:14

US3372089

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '1968'	System	29 Sep 2020 15:49:14

US3372089

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 1968'	System	29 Sep 2020 15:49:14

US3372089

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '1968'	System	29 Sep 2020 15:49:14

US3372089

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
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)	29 Sep 2020 15:50:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:50:40
Data point term sent to Coder	System	29 Sep 2020 15:50:19
User entered 'vasectomy'	Peter Jacob (b) (4)	29 Sep 2020 15:49:26

US3372089

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 1994'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:49:26

US3372089

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:49:26

US3372089

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:49:26

US3372089

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 1994'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:49:26

US3372089

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:49:26

US3372089

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 1994'	System	29 Sep 2020 15:49:26

US3372089

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '1994'	System	29 Sep 2020 15:49:26

US3372089

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 1994'	System	29 Sep 2020 15:49:26

US3372089

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '1994'	System	29 Sep 2020 15:49:26

US3372089

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:12:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:50:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:50:40
Data point term sent to Coder	System	29 Sep 2020 15:50:19
User entered 'obesity'	Peter Jacob (b) (4)	29 Sep 2020 15:49:50

US3372089

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 1994'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:49:50

US3372089

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:49:50

US3372089

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:12:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:49:50

US3372089

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 1994'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:49:50

US3372089

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:12:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:49:50

US3372089

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 1994'	System	29 Sep 2020 15:49:50

US3372089

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '1994'	System	29 Sep 2020 15:49:50

US3372089

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 1994'	System	29 Sep 2020 15:49:50

US3372089

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '1994'	System	29 Sep 2020 15:49:50

US3372089

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:12:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis, LLT: Dermatitis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 07:35:40
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 07:35:40
Data point term sent to Coder	System	29 Sep 2020 15:54:32
User entered 'bilateral upper extremity dermatoses'	Peter Jacob (b) (4)	29 Sep 2020 15:54:16

US3372089

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 2000'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:54:16

US3372089

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:54:16

US3372089

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:12:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	Peter Jacob (b) (4)	29 Sep 2020 15:54:16

US3372089

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:54:16

US3372089

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:12:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	Peter Jacob (b) (4)	29 Sep 2020 15:54:16

US3372089

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'Jan 2000'	System	29 Sep 2020 15:54:16

US3372089

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '2000'	System	29 Sep 2020 15:54:16

US3372089

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered empty.	System	29 Sep 2020 15:54:16

US3372089

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered empty.	System	29 Sep 2020 15:54:16

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 19:21:44

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '11 Aug 2020'	(b) (4) Peter Jacob (b) (4)	14 Aug 2020 19:21:44

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '14:40'	Peter Jacob (b) (4)	14 Aug 2020 19:21:44

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered '11 Aug 2020 14:40'	System	14 Aug 2020 19:21:44

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '175.5' cm	(b) (4) Peter Jacob (b) (4)	14 Aug 2020 19:21:44
DataPoint set to visible.	(b) (4) System	11 Aug 2020 18:16:53

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '98.1' kg	(b) (4) Peter Jacob (b) (4)	14 Aug 2020 19:21:44
DataPoint set to visible.	(b) (4) System	11 Aug 2020 18:16:53

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
Amendment Manager: User entered '31.85039'	System	16 Sep 2020 23:52:07
User entered '31.9'	System	14 Aug 2020 19:21:44
DataPoint set to visible.	System	11 Aug 2020 18:16:53

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'kg/m2'	System	14 Aug 2020 19:21:44
DataPoint set to visible.	System	11 Aug 2020 18:16:53

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 11:20:35
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:44:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:43:58
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:45:03
User entered '36' C	Peter Jacob (b) (4) (b) (4)	14 Aug 2020 19:21:44

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:43:58
User entered 'Oral (Oral)'	Peter Jacob (b) (4)	14 Aug 2020 19:21:44
	(b) (4)	

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	Peter Jacob (b) (4)	14 Aug 2020 19:21:44

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:43:58
User entered '66'	Peter Jacob (b) (4)	14 Aug 2020 19:21:44
	(b) (4)	

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'bpm'	System	14 Aug 2020 19:21:44

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:43:58
User entered '20'	Peter Jacob (b) (4)	14 Aug 2020 19:21:44
	(b) (4)	

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'breaths/min'	System	14 Aug 2020 19:21:44

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:43:58
User entered '140'	Peter Jacob (b) (4)	14 Aug 2020 19:21:44
	(b) (4)	

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'mmHg'	System	14 Aug 2020 19:21:44

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:43:58
User entered '88'	Peter Jacob (b) (4)	14 Aug 2020 19:21:44
	(b) (4)	

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User entered 'mmHg'	System	14 Aug 2020 19:21:44

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15

US3372089

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15

US3372089

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Aug 2020 19:24:16

US3372089

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:18:02
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 17:38:42
User entered '11 Aug 2020'	Peter Jacob (b) (4) (b) (4)	14 Aug 2020 19:24:16

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

[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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

[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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 18:19:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 18:19:33
User entered 'No (N)' reason for change: Per Query Resolution	Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:33
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 18:19:20
User entered empty.	Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

[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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

[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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

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 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'I'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:20

US3372089

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:30:15
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered (b) (6) apartment, where there is other workers.'	(b) (4) Kimarie Lee-Russell	11 Aug 2020 18:19:20

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:44

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '11 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:44

US3372089

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Clinic (Clinic)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 18:19:44

US3372089

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'VISIT1'	System	11 Aug 2020 18:19:44

US3372089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:29:32

US3372089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:37

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:38:39
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:38:39
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 19:29:32
User entered '185670' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:29:32

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:29:32

US3372089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 19:28:49

US3372089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 19:28:49

US3372089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:37

[Severe obesity \(body mass index > or = 40kg/m2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 19:28:49

US3372089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 19:28:49

US3372089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:37

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 19:28:49

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 11:20:30
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:55:25
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:55:14
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:45:13
User entered '175.5' cm	Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 14:55:14
User entered '98.1' kg	Peter Jacob (b) (4)	14 Aug 2020 20:20:06
	(b) (4)	

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 11:20:30
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:55:25
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:55:14
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:45:13
User entered '175.5' cm	Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 14:55:14
User entered '98.1' kg	Peter Jacob (b) (4)	14 Aug 2020 20:20:06
	(b) (4)	

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:20:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '11 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:20:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '14:40'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:20:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered '11 Aug 2020 14:40'	System	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '36' C	(b) (4) Peter Jacob (b) (4)	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '66'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'bpm'	System	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '20'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'breaths/min'	System	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '140'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'mmHg'	System	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '88'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'mmHg'	System	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 11:20:30
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:55:25
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:55:14
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:45:13
User entered '175.5' cm	Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:20:06

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 14:55:14
User entered '98.1' kg	Peter Jacob (b) (4)	14 Aug 2020 20:20:06
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '11 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
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) (4), (b) (6)	17 Aug 2020 09:54:37
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol post-dose vital signs must be collected at least 30 minutes after dose time' (Site from System).	Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:28:19
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).		14 Aug 2020 20:27:35
User entered '16:45'	Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered '11 Aug 2020 16:45'	System	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '36.2' C	(b) (4) Peter Jacob (b) (4)	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '66'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'bpm'	System	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '20'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'breaths/min'	System	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '138'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'mmHg'	System	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '83'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'mmHg'	System	14 Aug 2020 20:27:35

US3372089

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:28:27

US3372089

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '11 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:28:27

US3372089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 20:17:03

US3372089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 20:17:03

US3372089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 20:17:03

US3372089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 20:17:03

US3372089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '11 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 20:17:03

US3372089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '16:11'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 20:17:03

US3372089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered '11 Aug 2020 16:11'	System	11 Aug 2020 20:17:03

US3372089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kimarie Lee-Russell (b) (4)	11 Aug 2020 20:17:03

US3372089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'ONCE'	System	11 Aug 2020 20:17:03

US3372089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 20:17:03

US3372089

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Aug 2020 20:29:47

US3372089

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '11 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:29:47

US3372089

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '15:18'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:29:47

US3372089

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered '11 Aug 2020 15:18'	System	14 Aug 2020 20:29:47

US3372089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:12:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '11 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:29:57

US3372089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:29:57

US3372089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Aug 2020 20:29:57

US3372089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '15:17'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:29:57

US3372089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered '11 Aug 2020 15:17'	System	14 Aug 2020 20:29:57

US3372089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:29:57

US3372089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	14 Aug 2020 20:29:57

US3372089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:29:57

US3372089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered empty.	System	14 Aug 2020 20:29:57

US3372089

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 20:31:58

US3372089

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'I'	System	14 Aug 2020 20:31:58

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:46:15', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7dda2667-dcbd-4a98-814e-393fd16a42db'	System	11 Aug 2020 20:46:53
User entered 'Yes (Y)'	System	11 Aug 2020 20:46:53

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:46:25', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7dda2667-dcbd-4a98-814e-393fd16a42db'	System	11 Aug 2020 20:46:53
User entered '97.1'	System	11 Aug 2020 20:46:53

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:46:36', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7dda2667-dcbd-4a98-814e-393fd16a42db'	System	11 Aug 2020 20:46:53
User entered 'No (N)'	System	11 Aug 2020 20:46:53

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:46:50', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7dda2667-dcbd-4a98-814e-393fd16a42db'	System	11 Aug 2020 20:46:53
User entered '11 Aug 2020 16:46'	System	11 Aug 2020 20:46:53

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Aug 2020 16:31'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Aug 2020 19:01'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:39:10', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'aef16269-2ddf-47d6-b713-f5b2cfaedc34'	System	12 Aug 2020 14:40:19
User entered 'Yes (Y)'	System	12 Aug 2020 14:40:19

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:39:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'aef16269-2ddf-47d6-b713-f5b2cfaedc34'	System	12 Aug 2020 14:40:19
User entered '97.2'	System	12 Aug 2020 14:40:19

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:39:33', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'aef16269-2ddf-47d6-b713-f5b2cfaedc34'	System	12 Aug 2020 14:40:19
User entered 'Yes (Y)'	System	12 Aug 2020 14:40:19

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient has been contacted' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 14:15:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:40:01', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'aef16269-2ddf-47d6-b713-f5b2cfaedc34'	Peter Jacob (b) (4)	26 Aug 2020 19:35:57
User entered '1'	(b) (4)	
	System	12 Aug 2020 14:40:19
	System	12 Aug 2020 14:40:19
	System	12 Aug 2020 14:40:19

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:40:01', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'aef16269-2ddf-47d6-b713-f5b2cfaedc34'	System	12 Aug 2020 14:40:19
User entered '0'	System	12 Aug 2020 14:40:19

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:40:12', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'aef16269-2ddf-47d6-b713-f5b2cfaedc34'	System	12 Aug 2020 14:40:19
User entered '12 Aug 2020 10:40'	System	12 Aug 2020 14:40:19

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Aug 2020 19:56'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 2'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:50:14', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '756c8d85-aec8-4889-8f86-0f938fcdc48a'	System	12 Aug 2020 21:51:09
User entered 'Yes (Y)'	System	12 Aug 2020 21:51:09

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:50:25', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '756c8d85-aec8-4889-8f86-0f938fcdc48a'	System	12 Aug 2020 21:51:09
User entered '97.2'	System	12 Aug 2020 21:51:09

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:50:39', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '756c8d85-aec8-4889-8f86-0f938fcdc48a'	System	12 Aug 2020 21:51:09
User entered 'Yes (Y)'	System	12 Aug 2020 21:51:09

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient has been contacted' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 14:15:53
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Peter Jacob (b) (4)	26 Aug 2020 19:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:50:52', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '756c8d85-aec8-4889-8f86-0f938fcdc48a'	(b) (4)	
User entered '1'	System	12 Aug 2020 21:51:09
	System	12 Aug 2020 21:51:09
	System	12 Aug 2020 21:51:09

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:50:52', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '756c8d85-aec8-4889-8f86-0f938fcdc48a'	System	12 Aug 2020 21:51:09
User entered '0'	System	12 Aug 2020 21:51:09

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:51:04', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '756c8d85-aec8-4889-8f86-0f938fcdc48a'	System	12 Aug 2020 21:51:09
User entered '12 Aug 2020 17:51'	System	12 Aug 2020 21:51:09

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 3'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:22:41', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '889b33e6-b858-4e85-9c9a-306454fd96e1'	System	13 Aug 2020 20:23:19
User entered 'Yes (Y)'	System	13 Aug 2020 20:23:19

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:22:53', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '889b33e6-b858-4e85-9c9a-306454fd96e1'	System	13 Aug 2020 20:23:19
User entered '97.7'	System	13 Aug 2020 20:23:19

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:23:02', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '889b33e6-b858-4e85-9c9a-306454fd96e1'	System	13 Aug 2020 20:23:19
User entered 'No (N)'	System	13 Aug 2020 20:23:19

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:23:14', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '889b33e6-b858-4e85-9c9a-306454fd96e1'	System	13 Aug 2020 20:23:19
User entered '13 Aug 2020 16:23'	System	13 Aug 2020 20:23:19

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 4'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:19:03', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5b89779c-6ce8-4eed-a04e-58f2641a3fe7'	System	14 Aug 2020 21:20:36
User entered 'Yes (Y)'	System	14 Aug 2020 21:20:36

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:19:53', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5b89779c-6ce8-4eed-a04e-58f2641a3fe7'	System	14 Aug 2020 21:20:36
User entered '98.0'	System	14 Aug 2020 21:20:36

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:20:05', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5b89779c-6ce8-4eed-a04e-58f2641a3fe7'	System	14 Aug 2020 21:20:36
User entered 'Yes (Y)'	System	14 Aug 2020 21:20:36

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient has been contacted' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 14:16:03
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Peter Jacob (b) (4)	26 Aug 2020 19:36:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:20:21', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5b89779c-6ce8-4eed-a04e-58f2641a3fe7'	(b) (4)	
User entered '1'	System	14 Aug 2020 21:20:36
	System	14 Aug 2020 21:20:36
	System	14 Aug 2020 21:20:36

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:20:21', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5b89779c-6ce8-4eed-a04e-58f2641a3fe7'	System	14 Aug 2020 21:20:36
User entered '0'	System	14 Aug 2020 21:20:36

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:20:32', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5b89779c-6ce8-4eed-a04e-58f2641a3fe7'	System	14 Aug 2020 21:20:36
User entered '14 Aug 2020 17:20'	System	14 Aug 2020 21:20:36

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 5'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:20:22', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd51bd026-ea01-4aab-9f88-781164d73151'	System	15 Aug 2020 20:20:57
User entered 'Yes (Y)'	System	15 Aug 2020 20:20:57

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:20:36', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd51bd026-ea01-4aab-9f88-781164d73151'	System	15 Aug 2020 20:20:57
User entered '98.7'	System	15 Aug 2020 20:20:57

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:20:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd51bd026-ea01-4aab-9f88-781164d73151'	System	15 Aug 2020 20:20:57
User entered 'No (N)'	System	15 Aug 2020 20:20:57

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:20:53', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd51bd026-ea01-4aab-9f88-781164d73151'	System	15 Aug 2020 20:20:57
User entered '15 Aug 2020 16:20'	System	15 Aug 2020 20:20:57

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 6'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:12:05', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a7c7a9d1-a881-4391-b235-d51ae84c8184'	System	16 Aug 2020 20:12:33
User entered 'Yes (Y)'	System	16 Aug 2020 20:12:33

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:12:14', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a7c7a9d1-a881-4391-b235-d51ae84c8184'	System	16 Aug 2020 20:12:33
User entered '98.3'	System	16 Aug 2020 20:12:33

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:12:21', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a7c7a9d1-a881-4391-b235-d51ae84c8184'	System	16 Aug 2020 20:12:33
User entered 'No (N)'	System	16 Aug 2020 20:12:33

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:12:29', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a7c7a9d1-a881-4391-b235-d51ae84c8184'	System	16 Aug 2020 20:12:33
User entered '16 Aug 2020 16:12'	System	16 Aug 2020 20:12:33

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 7'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:51:43', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b3b66b68-8f06-42ff-8010-3a42af3774e5'	System	17 Aug 2020 20:52:09
User entered 'Yes (Y)'	System	17 Aug 2020 20:52:09

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:51:51', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b3b66b68-8f06-42ff-8010-3a42af3774e5'	System	17 Aug 2020 20:52:09
User entered '98.2'	System	17 Aug 2020 20:52:09

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:52:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b3b66b68-8f06-42ff-8010-3a42af3774e5'	System	17 Aug 2020 20:52:09
User entered 'No (N)'	System	17 Aug 2020 20:52:09

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:52:06', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b3b66b68-8f06-42ff-8010-3a42af3774e5'	System	17 Aug 2020 20:52:09
User entered '17 Aug 2020 16:52'	System	17 Aug 2020 20:52:09

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:47:06', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b3552413-6069-41a5-86be-612bd291d38c'	System	11 Aug 2020 20:47:45
User entered 'None (1)'	System	11 Aug 2020 20:47:45

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:47:14', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b3552413-6069-41a5-86be-612bd291d38c'	System	11 Aug 2020 20:47:45
User entered 'No (N)'	System	11 Aug 2020 20:47:45

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:47:19', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b3552413-6069-41a5-86be-612bd291d38c'	System	11 Aug 2020 20:47:45
User entered 'No (N)'	System	11 Aug 2020 20:47:45

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:47:34', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b3552413-6069-41a5-86be-612bd291d38c'	System	11 Aug 2020 20:47:45
User entered 'None (1)'	System	11 Aug 2020 20:47:45

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:47:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b3552413-6069-41a5-86be-612bd291d38c'	System	11 Aug 2020 20:47:45
User entered '11 Aug 2020 16:47'	System	11 Aug 2020 20:47:45

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Aug 2020 16:31'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Aug 2020 19:01'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:35:49', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ad4a2d48-c525-4f95-b714-e1041d069b98'	System	12 Aug 2020 14:37:00
User entered 'None (1)'	System	12 Aug 2020 14:37:00

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:35:57', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ad4a2d48-c525-4f95-b714-e1041d069b98'	System	12 Aug 2020 14:37:00
User entered 'No (N)'	System	12 Aug 2020 14:37:00

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:36:02', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ad4a2d48-c525-4f95-b714-e1041d069b98'	System	12 Aug 2020 14:37:00
User entered 'No (N)'	System	12 Aug 2020 14:37:00

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:36:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ad4a2d48-c525-4f95-b714-e1041d069b98'	System	12 Aug 2020 14:37:00
User entered 'None (1)'	System	12 Aug 2020 14:37:00

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:36:54', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ad4a2d48-c525-4f95-b714-e1041d069b98'	System	12 Aug 2020 14:37:00
User entered '12 Aug 2020 10:36'	System	12 Aug 2020 14:37:00

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Aug 2020 19:56'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 2'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:51:14', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '96e26805-b929-43e0-8a1e-8425e03d79bb'	System	12 Aug 2020 21:51:42
User entered 'None (1)'	System	12 Aug 2020 21:51:42

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:51:19', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '96e26805-b929-43e0-8a1e-8425e03d79bb'	System	12 Aug 2020 21:51:42
User entered 'No (N)'	System	12 Aug 2020 21:51:42

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:51:22', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '96e26805-b929-43e0-8a1e-8425e03d79bb'	System	12 Aug 2020 21:51:42
User entered 'No (N)'	System	12 Aug 2020 21:51:42

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:51:27', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '96e26805-b929-43e0-8a1e-8425e03d79bb'	System	12 Aug 2020 21:51:42
User entered 'None (1)'	System	12 Aug 2020 21:51:42

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:51:37', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '96e26805-b929-43e0-8a1e-8425e03d79bb'	System	12 Aug 2020 21:51:42
User entered '12 Aug 2020 17:51'	System	12 Aug 2020 21:51:42

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 3'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:23:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9d712327-0d4c-49e7-a47e-5fa326551ded'	System	13 Aug 2020 20:24:05
User entered 'None (1)'	System	13 Aug 2020 20:24:05

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:23:36', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9d712327-0d4c-49e7-a47e-5fa326551ded'	System	13 Aug 2020 20:24:05
User entered 'No (N)'	System	13 Aug 2020 20:24:05

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:23:40', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9d712327-0d4c-49e7-a47e-5fa326551ded'	System	13 Aug 2020 20:24:05
User entered 'No (N)'	System	13 Aug 2020 20:24:05

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:23:48', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9d712327-0d4c-49e7-a47e-5fa326551ded'	System	13 Aug 2020 20:24:05
User entered 'None (1)'	System	13 Aug 2020 20:24:05

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:24:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9d712327-0d4c-49e7-a47e-5fa326551ded'	System	13 Aug 2020 20:24:05
User entered '13 Aug 2020 16:24'	System	13 Aug 2020 20:24:05

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 4'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:20:46', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'eaa17b63-462b-4609-82f3-777664be0879'	System	14 Aug 2020 21:21:14
User entered 'None (1)'	System	14 Aug 2020 21:21:14

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:20:51', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'eaa17b63-462b-4609-82f3-777664be0879'	System	14 Aug 2020 21:21:14
User entered 'No (N)'	System	14 Aug 2020 21:21:14

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:20:57', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'eaa17b63-462b-4609-82f3-777664be0879'	System	14 Aug 2020 21:21:14
User entered 'No (N)'	System	14 Aug 2020 21:21:14

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:21:02', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'eaa17b63-462b-4609-82f3-777664be0879'	System	14 Aug 2020 21:21:14
User entered 'None (1)'	System	14 Aug 2020 21:21:14

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:21:09', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'eaa17b63-462b-4609-82f3-777664be0879'	System	14 Aug 2020 21:21:14
User entered '14 Aug 2020 17:21'	System	14 Aug 2020 21:21:14

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 5'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:21:16', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ebbbaa46-7986-4dba-8d73-74509d48e631'	System	15 Aug 2020 20:21:43
User entered 'None (1)'	System	15 Aug 2020 20:21:43

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:21:20', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ebbbaa46-7986-4dba-8d73-74509d48e631'	System	15 Aug 2020 20:21:43
User entered 'No (N)'	System	15 Aug 2020 20:21:43

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:21:24', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ebbbaa46-7986-4dba-8d73-74509d48e631'	System	15 Aug 2020 20:21:43
User entered 'No (N)'	System	15 Aug 2020 20:21:43

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:21:31', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ebbbaa46-7986-4dba-8d73-74509d48e631'	System	15 Aug 2020 20:21:43
User entered 'None (1)'	System	15 Aug 2020 20:21:43

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:21:36', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ebbbaa46-7986-4dba-8d73-74509d48e631'	System	15 Aug 2020 20:21:43
User entered '15 Aug 2020 16:21'	System	15 Aug 2020 20:21:43

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 6'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:12:37', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b96bf0de-3e43-411f-be5c-bf101dbdded3'	System	16 Aug 2020 20:13:01
User entered 'None (1)'	System	16 Aug 2020 20:13:01

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:12:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b96bf0de-3e43-411f-be5c-bf101dbdded3'	System	16 Aug 2020 20:13:01
User entered 'No (N)'	System	16 Aug 2020 20:13:01

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:12:46', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b96bf0de-3e43-411f-be5c-bf101dbdded3'	System	16 Aug 2020 20:13:01
User entered 'No (N)'	System	16 Aug 2020 20:13:01

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:12:52', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b96bf0de-3e43-411f-be5c-bf101dbdded3'	System	16 Aug 2020 20:13:01
User entered 'None (1)'	System	16 Aug 2020 20:13:01

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:12:56', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b96bf0de-3e43-411f-be5c-bf101dbdded3'	System	16 Aug 2020 20:13:01
User entered '16 Aug 2020 16:12'	System	16 Aug 2020 20:13:01

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 7'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:52:13', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bf57ee6d-878a-45d7-a1b9-1dc1ad1038'	System	17 Aug 2020 20:52:34
User entered 'None (1)'	System	17 Aug 2020 20:52:34

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:52:17', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bf57ee6d-878a-45d7-a1b9-1dc1ad1038'	System	17 Aug 2020 20:52:34
User entered 'No (N)'	System	17 Aug 2020 20:52:34

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:52:21', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bf57ee6d-878a-45d7-a1b9-1dc1ad1038'	System	17 Aug 2020 20:52:34
User entered 'No (N)'	System	17 Aug 2020 20:52:34

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:52:25', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bf57ee6d-878a-45d7-a1b9-1dc1ad1038'	System	17 Aug 2020 20:52:34
User entered 'None (1)'	System	17 Aug 2020 20:52:34

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:52:29', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bf57ee6d-878a-45d7-a1b9-1dcde1ad1038'	System	17 Aug 2020 20:52:34
User entered '17 Aug 2020 16:52'	System	17 Aug 2020 20:52:34

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:47:50', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7396a34c-6e39-4e16-b3df-a5145eb8e1d1'	System	11 Aug 2020 20:48:40
User entered 'None (0)'	System	11 Aug 2020 20:48:40

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:47:55', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7396a34c-6e39-4e16-b3df-a5145eb8e1d1'	System	11 Aug 2020 20:48:40
User entered 'None (0)'	System	11 Aug 2020 20:48:40

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:48:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7396a34c-6e39-4e16-b3df-a5145eb8e1d1'	System	11 Aug 2020 20:48:40
User entered 'None (0)'	System	11 Aug 2020 20:48:40

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:48:06', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7396a34c-6e39-4e16-b3df-a5145eb8e1d1'	System	11 Aug 2020 20:48:40
User entered 'None (0)'	System	11 Aug 2020 20:48:40

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:48:17', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7396a34c-6e39-4e16-b3df-a5145eb8e1d1'	System	11 Aug 2020 20:48:40
User entered 'None (0)'	System	11 Aug 2020 20:48:40

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:48:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7396a34c-6e39-4e16-b3df-a5145eb8e1d1'	System	11 Aug 2020 20:48:40
User entered 'None (0)'	System	11 Aug 2020 20:48:40

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:48:32', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7396a34c-6e39-4e16-b3df-a5145eb8e1d1'	System	11 Aug 2020 20:48:40
User entered 'No (N)'	System	11 Aug 2020 20:48:40

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-11T16:48:36', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7396a34c-6e39-4e16-b3df-a5145eb8e1d1'	System	11 Aug 2020 20:48:40
User entered '11 Aug 2020 16:48'	System	11 Aug 2020 20:48:40

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Aug 2020 16:31'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Aug 2020 19:01'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:37:12', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'afb7d819-0626-4864-96b8-7cef0286a2db'	System	12 Aug 2020 14:38:24
User entered 'None (0)'	System	12 Aug 2020 14:38:24

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:37:26', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'afb7d819-0626-4864-96b8-7cef0286a2db'	System	12 Aug 2020 14:38:24
User entered 'None (0)'	System	12 Aug 2020 14:38:24

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:37:41', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'afb7d819-0626-4864-96b8-7cef0286a2db'	System	12 Aug 2020 14:38:24
User entered 'No interference with activity (1)'	System	12 Aug 2020 14:38:24

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:37:50', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'afb7d819-0626-4864-96b8-7cef0286a2db'	System	12 Aug 2020 14:38:24
User entered 'No interference with activity (1)'	System	12 Aug 2020 14:38:24

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:37:56', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'afb7d819-0626-4864-96b8-7cef0286a2db'	System	12 Aug 2020 14:38:24
User entered 'None (0)'	System	12 Aug 2020 14:38:24

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:38:01', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'afb7d819-0626-4864-96b8-7cef0286a2db'	System	12 Aug 2020 14:38:24
User entered 'None (0)'	System	12 Aug 2020 14:38:24

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:38:11', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'afb7d819-0626-4864-96b8-7cef0286a2db'	System	12 Aug 2020 14:38:24
User entered 'No (N)'	System	12 Aug 2020 14:38:24

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T10:38:20', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'afb7d819-0626-4864-96b8-7cef0286a2db'	System	12 Aug 2020 14:38:24
User entered '12 Aug 2020 10:38'	System	12 Aug 2020 14:38:24

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Aug 2020 19:56'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 2'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:51:48', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8ad05537-9a9f-4a8d-b293-3e7e3193c5a6'	System	12 Aug 2020 21:52:50
User entered 'None (0)'	System	12 Aug 2020 21:52:50

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:51:52', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8ad05537-9a9f-4a8d-b293-3e7e3193c5a6'	System	12 Aug 2020 21:52:50
User entered 'None (0)'	System	12 Aug 2020 21:52:50

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:52:37', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8ad05537-9a9f-4a8d-b293-3e7e3193c5a6'	System	12 Aug 2020 21:52:50
User entered 'None (0)'	System	12 Aug 2020 21:52:50

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:52:12', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8ad05537-9a9f-4a8d-b293-3e7e3193c5a6'	System	12 Aug 2020 21:52:50
User entered 'None (0)'	System	12 Aug 2020 21:52:50

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:52:16', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8ad05537-9a9f-4a8d-b293-3e7e3193c5a6'	System	12 Aug 2020 21:52:50
User entered 'None (0)'	System	12 Aug 2020 21:52:50

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:52:20', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8ad05537-9a9f-4a8d-b293-3e7e3193c5a6'	System	12 Aug 2020 21:52:50
User entered 'None (0)'	System	12 Aug 2020 21:52:50

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:52:29', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8ad05537-9a9f-4a8d-b293-3e7e3193c5a6'	System	12 Aug 2020 21:52:50
User entered 'No (N)'	System	12 Aug 2020 21:52:50

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-12T17:52:44', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8ad05537-9a9f-4a8d-b293-3e7e3193c5a6'	System	12 Aug 2020 21:52:50
User entered '12 Aug 2020 17:52'	System	12 Aug 2020 21:52:50

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 3'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:24:44', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '715eba8b-8745-405b-9e20-acbb0e432b8e'	System	13 Aug 2020 20:25:55
User entered 'None (0)'	System	13 Aug 2020 20:25:55

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:24:59', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '715eba8b-8745-405b-9e20-acbb0e432b8e'	System	13 Aug 2020 20:25:55
User entered 'No interference with activity (1)'	System	13 Aug 2020 20:25:55

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:25:06', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '715eba8b-8745-405b-9e20-acbb0e432b8e'	System	13 Aug 2020 20:25:55
User entered 'No interference with activity (1)'	System	13 Aug 2020 20:25:55

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:25:20', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '715eba8b-8745-405b-9e20-acbb0e432b8e'	System	13 Aug 2020 20:25:55
User entered 'No interference with activity (1)'	System	13 Aug 2020 20:25:55

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:25:24', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '715eba8b-8745-405b-9e20-acbb0e432b8e'	System	13 Aug 2020 20:25:55
User entered 'None (0)'	System	13 Aug 2020 20:25:55

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:25:28', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '715eba8b-8745-405b-9e20-acbb0e432b8e'	System	13 Aug 2020 20:25:55
User entered 'None (0)'	System	13 Aug 2020 20:25:55

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:25:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '715eba8b-8745-405b-9e20-acbb0e432b8e'	System	13 Aug 2020 20:25:55
User entered 'No (N)'	System	13 Aug 2020 20:25:55

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-13T16:25:48', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '715eba8b-8745-405b-9e20-acbb0e432b8e'	System	13 Aug 2020 20:25:55
User entered '13 Aug 2020 16:25'	System	13 Aug 2020 20:25:55

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 4'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:21:19', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bf512f93-42cf-4cfe-9652-cf34134d32e8'	System	14 Aug 2020 21:22:02
User entered 'None (0)'	System	14 Aug 2020 21:22:02

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:21:25', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bf512f93-42cf-4cfe-9652-cf34134d32e8'	System	14 Aug 2020 21:22:02
User entered 'No interference with activity (1)'	System	14 Aug 2020 21:22:02

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:21:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bf512f93-42cf-4cfe-9652-cf34134d32e8'	System	14 Aug 2020 21:22:02
User entered 'No interference with activity (1)'	System	14 Aug 2020 21:22:02

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:21:34', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bf512f93-42cf-4cfe-9652-cf34134d32e8'	System	14 Aug 2020 21:22:02
User entered 'No interference with activity (1)'	System	14 Aug 2020 21:22:02

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:21:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bf512f93-42cf-4cfe-9652-cf34134d32e8'	System	14 Aug 2020 21:22:02
User entered 'None (0)'	System	14 Aug 2020 21:22:02

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:21:41', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bf512f93-42cf-4cfe-9652-cf34134d32e8'	System	14 Aug 2020 21:22:02
User entered 'None (0)'	System	14 Aug 2020 21:22:02

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:21:54', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bf512f93-42cf-4cfe-9652-cf34134d32e8'	System	14 Aug 2020 21:22:02
User entered 'No (N)'	System	14 Aug 2020 21:22:02

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-14T17:21:58', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bf512f93-42cf-4cfe-9652-cf34134d32e8'	System	14 Aug 2020 21:22:02
User entered '14 Aug 2020 17:21'	System	14 Aug 2020 21:22:02

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 5'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:21:44', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '075807c3-e744-4f9f-aeb1-651e2be2a76c'	System	15 Aug 2020 20:22:21
User entered 'None (0)'	System	15 Aug 2020 20:22:21

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:21:50', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '075807c3-e744-4f9f-aeb1-651e2be2a76c'	System	15 Aug 2020 20:22:21
User entered 'No interference with activity (1)'	System	15 Aug 2020 20:22:21

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:21:54', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '075807c3-e744-4f9f-aeb1-651e2be2a76c'	System	15 Aug 2020 20:22:21
User entered 'No interference with activity (1)'	System	15 Aug 2020 20:22:21

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:22:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '075807c3-e744-4f9f-aeb1-651e2be2a76c'	System	15 Aug 2020 20:22:21
User entered 'No interference with activity (1)'	System	15 Aug 2020 20:22:21

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:22:05', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '075807c3-e744-4f9f-aeb1-651e2be2a76c'	System	15 Aug 2020 20:22:21
User entered 'None (0)'	System	15 Aug 2020 20:22:21

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:22:09', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '075807c3-e744-4f9f-aeb1-651e2be2a76c'	System	15 Aug 2020 20:22:21
User entered 'None (0)'	System	15 Aug 2020 20:22:21

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:22:14', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '075807c3-e744-4f9f-aeb1-651e2be2a76c'	System	15 Aug 2020 20:22:21
User entered 'No (N)'	System	15 Aug 2020 20:22:21

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-15T16:22:18', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '075807c3-e744-4f9f-aeb1-651e2be2a76c'	System	15 Aug 2020 20:22:21
User entered '15 Aug 2020 16:22'	System	15 Aug 2020 20:22:21

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 6'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:13:06', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2b6cff0a-581b-449b-8959-dfc1b67da538'	System	16 Aug 2020 20:13:45
User entered 'None (0)'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:13:11', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2b6cff0a-581b-449b-8959-dfc1b67da538'	System	16 Aug 2020 20:13:45
User entered 'No interference with activity (1)'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:13:20', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2b6cff0a-581b-449b-8959-dfc1b67da538'	System	16 Aug 2020 20:13:45
User entered 'No interference with activity (1)'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:13:25', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2b6cff0a-581b-449b-8959-dfc1b67da538'	System	16 Aug 2020 20:13:45
User entered 'No interference with activity (1)'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:13:29', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2b6cff0a-581b-449b-8959-dfc1b67da538'	System	16 Aug 2020 20:13:45
User entered 'None (0)'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:13:33', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2b6cff0a-581b-449b-8959-dfc1b67da538'	System	16 Aug 2020 20:13:45
User entered 'None (0)'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:13:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2b6cff0a-581b-449b-8959-dfc1b67da538'	System	16 Aug 2020 20:13:45
User entered 'No (N)'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-16T16:13:41', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2b6cff0a-581b-449b-8959-dfc1b67da538'	System	16 Aug 2020 20:13:45
User entered '16 Aug 2020 16:13'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 7'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:52:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '1765fa58-9f80-490d-ae61-7eb112b33082'	System	17 Aug 2020 20:53:19
User entered 'None (0)'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:52:44', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '1765fa58-9f80-490d-ae61-7eb112b33082'	System	17 Aug 2020 20:53:19
User entered 'No interference with activity (1)'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:52:48', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '1765fa58-9f80-490d-ae61-7eb112b33082'	System	17 Aug 2020 20:53:19
User entered 'No interference with activity (1)'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:52:56', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '1765fa58-9f80-490d-ae61-7eb112b33082'	System	17 Aug 2020 20:53:19
User entered 'No interference with activity (1)'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:53:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '1765fa58-9f80-490d-ae61-7eb112b33082'	System	17 Aug 2020 20:53:19
User entered 'None (0)'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:53:05', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '1765fa58-9f80-490d-ae61-7eb112b33082'	System	17 Aug 2020 20:53:19
User entered 'None (0)'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:53:10', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '1765fa58-9f80-490d-ae61-7eb112b33082'	System	17 Aug 2020 20:53:19
User entered 'No (N)'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-17T16:53:13', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '1765fa58-9f80-490d-ae61-7eb112b33082'	System	17 Aug 2020 20:53:19
User entered '17 Aug 2020 16:53'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	16 Aug 2020 20:13:45
User entered 'Day 8'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-18T15:52:54', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd19cd3ab-4ae9-4f25-a0ed-96df132523d1'	System	18 Aug 2020 19:53:12
User entered 'No interference with activity (1)'	System	18 Aug 2020 19:53:12

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-18T15:53:04', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd19cd3ab-4ae9-4f25-a0ed-96df132523d1'	System	18 Aug 2020 19:53:12
User entered '18 Aug 2020 15:53'	System	18 Aug 2020 19:53:12

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	17 Aug 2020 20:53:19
User entered 'Day 9'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-19T12:01:26', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '744a1a1c-0fd1-4d99-b188-214aa280c284'	System	19 Aug 2020 16:01:47
User entered 'No interference with activity (1)'	System	19 Aug 2020 16:01:47

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-19T12:01:32', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '744a1a1c-0fd1-4d99-b188-214aa280c284'	System	19 Aug 2020 16:01:47
User entered '19 Aug 2020 12:01'	System	19 Aug 2020 16:01:47

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	18 Aug 2020 19:53:12
User entered 'Day 10'	System	18 Aug 2020 19:53:12

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-20T16:36:39', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'dff87ddc-5811-473b-b571-a0102dbcc639'	System	20 Aug 2020 20:36:48
User entered 'No interference with activity (1)'	System	20 Aug 2020 20:36:48

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-20T16:36:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'dff87ddc-5811-473b-b571-a0102dbcc639'	System	20 Aug 2020 20:36:48
User entered '20 Aug 2020 16:36'	System	20 Aug 2020 20:36:48

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 19:53:12

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 19:53:12

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	19 Aug 2020 16:01:47
User entered 'Day 11'	System	19 Aug 2020 16:01:47

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-21T17:44:50', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd253692a-f2ae-46f6-8bb9-957973dd06e7'	System	21 Aug 2020 21:44:56
User entered 'No interference with activity (1)'	System	21 Aug 2020 21:44:56

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-21T17:44:52', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd253692a-f2ae-46f6-8bb9-957973dd06e7'	System	21 Aug 2020 21:44:56
User entered '21 Aug 2020 17:44'	System	21 Aug 2020 21:44:56

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 16:01:47

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 16:01:47

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	20 Aug 2020 20:36:48
User entered 'Day 12'	System	20 Aug 2020 20:36:48

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-22T12:05:19', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ad80d5b8-045b-486c-bc1b-e7451fc28e10'	System	22 Aug 2020 16:05:28
User entered 'No interference with activity (1)'	System	22 Aug 2020 16:05:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-22T12:05:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ad80d5b8-045b-486c-bc1b-e7451fc28e10'	System	22 Aug 2020 16:05:28
User entered '22 Aug 2020 12:05'	System	22 Aug 2020 16:05:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:36:48

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:36:48

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	21 Aug 2020 21:44:56
User entered 'Day 13'	System	21 Aug 2020 21:44:56

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-23T12:25:33', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a2c327c9-f8f0-48e8-991d-b79583985831'	System	23 Aug 2020 16:25:47
User entered 'No interference with activity (1)'	System	23 Aug 2020 16:25:47

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-23T12:25:35', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a2c327c9-f8f0-48e8-991d-b79583985831'	System	23 Aug 2020 16:25:47
User entered '23 Aug 2020 12:25'	System	23 Aug 2020 16:25:47

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 21:44:56

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 21:44:56

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	22 Aug 2020 16:05:28
User entered 'Day 14'	System	22 Aug 2020 16:05:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-24T16:52:58', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9be904f5-d4d1-4d6c-9fef-89ead326ee50'	System	24 Aug 2020 20:53:10
User entered 'No interference with activity (1)'	System	24 Aug 2020 20:53:10

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-24T16:53:03', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9be904f5-d4d1-4d6c-9fef-89ead326ee50'	System	24 Aug 2020 20:53:10
User entered '24 Aug 2020 16:53'	System	24 Aug 2020 20:53:10

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 16:05:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 16:05:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	23 Aug 2020 16:25:47
User entered 'Day 15'	System	23 Aug 2020 16:25:47

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-25T12:52:40', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '850f91f1-5f37-4b97-a91a-7a2aab6b0419'	System	25 Aug 2020 16:52:48
User entered 'No interference with activity (1)'	System	25 Aug 2020 16:52:48

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-25T12:52:43', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '850f91f1-5f37-4b97-a91a-7a2aab6b0419'	System	25 Aug 2020 16:52:48
User entered '25 Aug 2020 12:52'	System	25 Aug 2020 16:52:48

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 16:25:47

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 16:25:47

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	24 Aug 2020 20:53:10
User entered 'Day 16'	System	24 Aug 2020 20:53:10

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-26T12:07:04', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '970993db-f35f-4654-8975-1ee4abab696d'	System	26 Aug 2020 16:07:09
User entered 'No interference with activity (1)'	System	26 Aug 2020 16:07:09

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-26T12:07:06', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '970993db-f35f-4654-8975-1ee4abab696d'	System	26 Aug 2020 16:07:09
User entered '26 Aug 2020 12:07'	System	26 Aug 2020 16:07:09

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:53:10

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:53:10

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	25 Aug 2020 16:52:48
User entered 'Day 17'	System	25 Aug 2020 16:52:48

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-27T12:28:16', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd931efdb-a804-4a11-8a5f-1de3f7472fbd'	System	27 Aug 2020 16:28:22
User entered 'No interference with activity (1)'	System	27 Aug 2020 16:28:22

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-27T12:28:18', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd931efdb-a804-4a11-8a5f-1de3f7472fbd'	System	27 Aug 2020 16:28:22
User entered '27 Aug 2020 12:28'	System	27 Aug 2020 16:28:22

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 16:52:48

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 16:52:48

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	26 Aug 2020 16:07:09
User entered 'Day 18'	System	26 Aug 2020 16:07:09

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-28T12:02:31', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'c8e00b50-31de-46df-a7e2-bc641f56d1de'	System	28 Aug 2020 16:03:51
User entered 'No interference with activity (1)'	System	28 Aug 2020 16:03:51

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-28T12:02:34', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'c8e00b50-31de-46df-a7e2-bc641f56d1de'	System	28 Aug 2020 16:03:51
User entered '28 Aug 2020 12:02'	System	28 Aug 2020 16:03:51

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:07:09

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:07:09

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	27 Aug 2020 16:28:22
User entered 'Day 19'	System	27 Aug 2020 16:28:22

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-29T15:31:09', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ae5c5586-d04f-4dcc-ac48-ae077e0f5eff'	System	29 Aug 2020 19:31:17
User entered 'No interference with activity (1)'	System	29 Aug 2020 19:31:17

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-29T15:31:13', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ae5c5586-d04f-4dcc-ac48-ae077e0f5eff'	System	29 Aug 2020 19:31:17
User entered '29 Aug 2020 15:31'	System	29 Aug 2020 19:31:17

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:28:22

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:28:22

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	28 Aug 2020 16:03:51
User entered 'Day 20'	System	28 Aug 2020 16:03:51

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-30T12:08:36', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '574979f5-f421-4b35-9077-09591ad5c3b9'	System	30 Aug 2020 16:08:44
User entered 'No interference with activity (1)'	System	30 Aug 2020 16:08:44

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-30T12:08:39', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '574979f5-f421-4b35-9077-09591ad5c3b9'	System	30 Aug 2020 16:08:44
User entered '30 Aug 2020 12:08'	System	30 Aug 2020 16:08:44

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:03:51

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:03:51

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	29 Aug 2020 19:31:17
User entered 'Day 21'	System	29 Aug 2020 19:31:17

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-31T14:17:54', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '87be6dc1-7e89-4c48-b06d-ba10deb9e032'	System	31 Aug 2020 18:18:01
User entered 'No interference with activity (1)'	System	31 Aug 2020 18:18:01

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-31T14:17:56', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '87be6dc1-7e89-4c48-b06d-ba10deb9e032'	System	31 Aug 2020 18:18:01
User entered '31 Aug 2020 14:17'	System	31 Aug 2020 18:18:01

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 19:31:17

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 19:31:17

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	30 Aug 2020 16:08:44
User entered 'Day 22'	System	30 Aug 2020 16:08:44

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-01T16:57:21', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '491d582e-f68f-47a6-99a5-088de954a3f6'	System	01 Sep 2020 20:57:28
User entered 'No interference with activity (1)'	System	01 Sep 2020 20:57:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-01T16:57:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '491d582e-f68f-47a6-99a5-088de954a3f6'	System	01 Sep 2020 20:57:28
User entered '01 Sep 2020 16:57'	System	01 Sep 2020 20:57:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 16:08:44

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 16:08:44

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	31 Aug 2020 18:18:01
User entered 'Day 23'	System	31 Aug 2020 18:18:01

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-02T12:05:44', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3984556a-300f-40d8-bd18-12cf2e6b396a'	System	02 Sep 2020 16:05:58
User entered 'No interference with activity (1)'	System	02 Sep 2020 16:05:58

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-02T12:05:50', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3984556a-300f-40d8-bd18-12cf2e6b396a'	System	02 Sep 2020 16:05:58
User entered '02 Sep 2020 12:05'	System	02 Sep 2020 16:05:58

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:18:01

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:18:01

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	01 Sep 2020 20:57:28
User entered 'Day 24'	System	01 Sep 2020 20:57:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-03T16:04:22', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '86e68709-8630-409b-a228-7fb4b9f017ca'	System	03 Sep 2020 20:04:28
User entered 'No interference with activity (1)'	System	03 Sep 2020 20:04:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-03T16:04:24', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '86e68709-8630-409b-a228-7fb4b9f017ca'	System	03 Sep 2020 20:04:28
User entered '03 Sep 2020 16:04'	System	03 Sep 2020 20:04:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:57:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:57:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	02 Sep 2020 16:05:58
User entered 'Day 25'	System	02 Sep 2020 16:05:58

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-04T12:20:43', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '75f9b68f-7c21-4e5f-a007-7a0b5f259bcb'	System	04 Sep 2020 16:20:52
User entered 'No interference with activity (1)'	System	04 Sep 2020 16:20:52

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-04T12:20:46', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '75f9b68f-7c21-4e5f-a007-7a0b5f259bcb'	System	04 Sep 2020 16:20:52
User entered '04 Sep 2020 12:20'	System	04 Sep 2020 16:20:52

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:05:58

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:05:58

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	03 Sep 2020 20:04:28
User entered 'Day 26'	System	03 Sep 2020 20:04:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-05T12:01:26', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8a4ef6fd-c633-40cd-9085-30737799f437'	System	05 Sep 2020 16:02:18
User entered 'No interference with activity (1)'	System	05 Sep 2020 16:02:18

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-05T12:01:28', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8a4ef6fd-c633-40cd-9085-30737799f437'	System	05 Sep 2020 16:02:18
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 16:02:18

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 20:04:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 20:04:28

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	04 Sep 2020 16:20:52
User entered 'Day 27'	System	04 Sep 2020 16:20:52

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T04:51:54', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '321e5f43-5814-4f39-81c4-4e1a6f568395'	System	07 Sep 2020 08:52:33
User entered 'No interference with activity (1)'	System	07 Sep 2020 08:52:33

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T04:51:57', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '321e5f43-5814-4f39-81c4-4e1a6f568395'	System	07 Sep 2020 08:52:33
User entered '07 Sep 2020 04:51'	System	07 Sep 2020 08:52:33

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 16:20:52

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 16:20:52

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	05 Sep 2020 16:02:18
User entered 'Day 28'	System	05 Sep 2020 16:02:18

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T12:45:09', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '67e7b15c-fa28-47e7-90bd-fae887032890'	System	07 Sep 2020 16:45:14
User entered 'No interference with activity (1)'	System	07 Sep 2020 16:45:14

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T12:45:11', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '67e7b15c-fa28-47e7-90bd-fae887032890'	System	07 Sep 2020 16:45:14
User entered '07 Sep 2020 12:45'	System	07 Sep 2020 16:45:14

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 16:02:18

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 16:02:18

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	07 Sep 2020 08:52:33
User entered 'Day 29'	System	07 Sep 2020 08:52:33

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-08T16:38:57', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '200faf2b-64c5-44a8-972c-13f3d9363b2e'	System	08 Sep 2020 20:39:07
User entered 'No interference with activity (1)'	System	08 Sep 2020 20:39:07

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-08T16:39:01', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '200faf2b-64c5-44a8-972c-13f3d9363b2e'	System	08 Sep 2020 20:39:07
User entered '08 Sep 2020 16:39'	System	08 Sep 2020 20:39:07

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 08:52:33

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 08:52:33

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	07 Sep 2020 16:45:14
User entered 'Day 30'	System	07 Sep 2020 16:45:14

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T12:00:59', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a43929fe-192c-484c-9fc4-4d962211e526'	System	09 Sep 2020 16:01:51
User entered 'No interference with activity (1)'	System	09 Sep 2020 16:01:51

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T12:01:01', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a43929fe-192c-484c-9fc4-4d962211e526'	System	09 Sep 2020 16:01:51
User entered '09 Sep 2020 12:01'	System	09 Sep 2020 16:01:51

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 16:45:14

US3372089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 16:45:14

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	16 Aug 2020 20:13:45
User entered 'Day 8'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-18T15:53:14', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '646c0036-137d-40a6-8597-6c96045b804e'	System	18 Aug 2020 19:53:23
User entered 'No interference with activity (1)'	System	18 Aug 2020 19:53:23

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-18T15:53:18', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '646c0036-137d-40a6-8597-6c96045b804e'	System	18 Aug 2020 19:53:23
User entered '18 Aug 2020 15:53'	System	18 Aug 2020 19:53:23

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	17 Aug 2020 20:53:19
User entered 'Day 9'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-19T12:01:39', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '19135f5c-0c76-475c-9491-b45e629d6110'	System	19 Aug 2020 16:01:56
User entered 'No interference with activity (1)'	System	19 Aug 2020 16:01:56

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-19T12:01:43', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '19135f5c-0c76-475c-9491-b45e629d6110'	System	19 Aug 2020 16:01:56
User entered '19 Aug 2020 12:01'	System	19 Aug 2020 16:01:56

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	18 Aug 2020 19:53:23
User entered 'Day 10'	System	18 Aug 2020 19:53:23

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-20T16:36:47', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ef010194-5f9c-41da-9a65-75bb6716fb37'	System	20 Aug 2020 20:36:55
User entered 'No interference with activity (1)'	System	20 Aug 2020 20:36:55

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-20T16:36:51', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ef010194-5f9c-41da-9a65-75bb6716fb37'	System	20 Aug 2020 20:36:55
User entered '20 Aug 2020 16:36'	System	20 Aug 2020 20:36:55

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 19:53:23

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 19:53:23

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	19 Aug 2020 16:01:56
User entered 'Day 11'	System	19 Aug 2020 16:01:56

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-21T17:44:58', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ee49b960-3490-4723-8ef6-c16eb22f545e'	System	21 Aug 2020 21:45:05
User entered 'No interference with activity (1)'	System	21 Aug 2020 21:45:05

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-21T17:45:02', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ee49b960-3490-4723-8ef6-c16eb22f545e'	System	21 Aug 2020 21:45:05
User entered '21 Aug 2020 17:45'	System	21 Aug 2020 21:45:05

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 16:01:56

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 16:01:56

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	20 Aug 2020 20:36:55
User entered 'Day 12'	System	20 Aug 2020 20:36:55

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-22T12:05:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b6ecc5de-11d0-426d-a4d2-bc31a974bd58'	System	22 Aug 2020 16:05:39
User entered 'No interference with activity (1)'	System	22 Aug 2020 16:05:39

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-22T12:05:33', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b6ecc5de-11d0-426d-a4d2-bc31a974bd58'	System	22 Aug 2020 16:05:39
User entered '22 Aug 2020 12:05'	System	22 Aug 2020 16:05:39

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:36:55

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:36:55

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	21 Aug 2020 21:45:05
User entered 'Day 13'	System	21 Aug 2020 21:45:05

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-23T12:25:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '43431a52-d024-4348-aaf7-35fe19063db6'	System	23 Aug 2020 16:25:48
User entered 'No interference with activity (1)'	System	23 Aug 2020 16:25:48

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-23T12:25:44', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '43431a52-d024-4348-aaf7-35fe19063db6'	System	23 Aug 2020 16:25:48
User entered '23 Aug 2020 12:25'	System	23 Aug 2020 16:25:48

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 21:45:05

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 21:45:05

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	22 Aug 2020 16:05:39
User entered 'Day 14'	System	22 Aug 2020 16:05:39

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-24T16:53:09', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0e050377-126d-4f05-82f7-9ab3b28abde1'	System	24 Aug 2020 20:53:18
User entered 'No interference with activity (1)'	System	24 Aug 2020 20:53:18

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-24T16:53:12', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0e050377-126d-4f05-82f7-9ab3b28abde1'	System	24 Aug 2020 20:53:18
User entered '24 Aug 2020 16:53'	System	24 Aug 2020 20:53:18

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 16:05:39

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 16:05:39

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	23 Aug 2020 16:25:48
User entered 'Day 15'	System	23 Aug 2020 16:25:48

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-25T12:52:51', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5a2b91ac-f65d-43e7-8852-bd61eb0e3849'	System	25 Aug 2020 16:52:56
User entered 'No interference with activity (1)'	System	25 Aug 2020 16:52:56

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-25T12:52:53', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5a2b91ac-f65d-43e7-8852-bd61eb0e3849'	System	25 Aug 2020 16:52:56
User entered '25 Aug 2020 12:52'	System	25 Aug 2020 16:52:56

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 16:25:48

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 16:25:48

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	24 Aug 2020 20:53:18
User entered 'Day 16'	System	24 Aug 2020 20:53:18

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-26T12:07:11', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5a8548b0-8b0d-4e2b-975c-97977dc2ab38'	System	26 Aug 2020 16:07:19
User entered 'No interference with activity (1)'	System	26 Aug 2020 16:07:19

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-26T12:07:15', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5a8548b0-8b0d-4e2b-975c-97977dc2ab38'	System	26 Aug 2020 16:07:19
User entered '26 Aug 2020 12:07'	System	26 Aug 2020 16:07:19

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:53:18

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:53:18

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	25 Aug 2020 16:52:56
User entered 'Day 17'	System	25 Aug 2020 16:52:56

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-27T12:28:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'eb57fd8c-ba04-45f1-9877-cd9472d74cff'	System	27 Aug 2020 16:28:30
User entered 'No interference with activity (1)'	System	27 Aug 2020 16:28:30

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-27T12:28:26', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'eb57fd8c-ba04-45f1-9877-cd9472d74cff'	System	27 Aug 2020 16:28:30
User entered '27 Aug 2020 12:28'	System	27 Aug 2020 16:28:30

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 16:52:56

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 16:52:56

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	26 Aug 2020 16:07:19
User entered 'Day 18'	System	26 Aug 2020 16:07:19

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-28T12:02:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '63e7f1fa-0587-4787-aa01-f095d3fc795a'	System	28 Aug 2020 16:03:55
User entered 'No interference with activity (1)'	System	28 Aug 2020 16:03:55

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-28T12:02:41', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '63e7f1fa-0587-4787-aa01-f095d3fc795a'	System	28 Aug 2020 16:03:55
User entered '28 Aug 2020 12:02'	System	28 Aug 2020 16:03:55

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:07:19

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:07:19

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	27 Aug 2020 16:28:30
User entered 'Day 19'	System	27 Aug 2020 16:28:30

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-29T15:31:18', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5578a0a2-9ed2-4fe7-a82c-4c15399fccdd'	System	29 Aug 2020 19:31:25
User entered 'No interference with activity (1)'	System	29 Aug 2020 19:31:25

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-29T15:31:21', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5578a0a2-9ed2-4fe7-a82c-4c15399fccdd'	System	29 Aug 2020 19:31:25
User entered '29 Aug 2020 15:31'	System	29 Aug 2020 19:31:25

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:28:30

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:28:30

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	28 Aug 2020 16:03:55
User entered 'Day 20'	System	28 Aug 2020 16:03:55

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-30T12:08:44', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9cb18aed-e18c-43f9-adeb-c008180ba04a'	System	30 Aug 2020 16:08:49
User entered 'No interference with activity (1)'	System	30 Aug 2020 16:08:49

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-30T12:08:47', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9cb18aed-e18c-43f9-adeb-c008180ba04a'	System	30 Aug 2020 16:08:49
User entered '30 Aug 2020 12:08'	System	30 Aug 2020 16:08:49

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:03:55

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:03:55

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	29 Aug 2020 19:31:25
User entered 'Day 21'	System	29 Aug 2020 19:31:25

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-31T14:18:01', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b06d6812-0ae1-4ce5-bd02-b28693d82fd9'	System	31 Aug 2020 18:18:08
User entered 'No interference with activity (1)'	System	31 Aug 2020 18:18:08

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-31T14:18:03', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b06d6812-0ae1-4ce5-bd02-b28693d82fd9'	System	31 Aug 2020 18:18:08
User entered '31 Aug 2020 14:18'	System	31 Aug 2020 18:18:08

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 19:31:25

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 19:31:25

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	30 Aug 2020 16:08:49
User entered 'Day 22'	System	30 Aug 2020 16:08:49

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-01T16:57:29', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '842a76a2-47dd-4100-92ca-5b31f0044e3c'	System	01 Sep 2020 20:57:33
User entered 'No interference with activity (1)'	System	01 Sep 2020 20:57:33

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-01T16:57:31', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '842a76a2-47dd-4100-92ca-5b31f0044e3c'	System	01 Sep 2020 20:57:33
User entered '01 Sep 2020 16:57'	System	01 Sep 2020 20:57:33

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 16:08:49

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 16:08:49

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	31 Aug 2020 18:18:08
User entered 'Day 23'	System	31 Aug 2020 18:18:08

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-02T12:05:56', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '4ade7700-b628-4cf6-9d6f-5645d00d4d35'	System	02 Sep 2020 16:06:06
User entered 'No interference with activity (1)'	System	02 Sep 2020 16:06:06

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-02T12:05:59', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '4ade7700-b628-4cf6-9d6f-5645d00d4d35'	System	02 Sep 2020 16:06:06
User entered '02 Sep 2020 12:05'	System	02 Sep 2020 16:06:06

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:18:08

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:18:08

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	01 Sep 2020 20:57:33
User entered 'Day 24'	System	01 Sep 2020 20:57:33

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-03T16:04:27', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0e275861-ea71-48f2-aaa6-3cd9ca7cfa8d'	System	03 Sep 2020 20:04:45
User entered 'No interference with activity (1)'	System	03 Sep 2020 20:04:45

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-03T16:04:31', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0e275861-ea71-48f2-aaa6-3cd9ca7cfa8d'	System	03 Sep 2020 20:04:45
User entered '03 Sep 2020 16:04'	System	03 Sep 2020 20:04:45

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:57:33

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:57:33

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	02 Sep 2020 16:06:06
User entered 'Day 25'	System	02 Sep 2020 16:06:06

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-04T12:20:53', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '144b0546-a381-42cb-9144-5eceb8cd16c0'	System	04 Sep 2020 16:20:59
User entered 'No interference with activity (1)'	System	04 Sep 2020 16:20:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-04T12:20:56', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '144b0546-a381-42cb-9144-5eceb8cd16c0'	System	04 Sep 2020 16:20:59
User entered '04 Sep 2020 12:20'	System	04 Sep 2020 16:20:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:06:06

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:06:06

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	03 Sep 2020 20:04:45
User entered 'Day 26'	System	03 Sep 2020 20:04:45

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-05T12:01:32', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '61d52daf-ce9c-45dc-946d-f4fef14e8bcb'	System	05 Sep 2020 16:02:31
User entered 'No interference with activity (1)'	System	05 Sep 2020 16:02:31

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-05T12:01:35', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '61d52daf-ce9c-45dc-946d-f4fef14e8bcb'	System	05 Sep 2020 16:02:31
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 16:02:31

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 20:04:45

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 20:04:45

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	04 Sep 2020 16:20:59
User entered 'Day 27'	System	04 Sep 2020 16:20:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T04:52:02', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'db7c1ee6-eb7e-421e-a628-aed2318ddc2b'	System	07 Sep 2020 08:52:32
User entered 'No interference with activity (1)'	System	07 Sep 2020 08:52:32

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T04:52:05', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'db7c1ee6-eb7e-421e-a628-aed2318ddc2b'	System	07 Sep 2020 08:52:32
User entered '07 Sep 2020 04:52'	System	07 Sep 2020 08:52:32

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 16:20:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 16:20:59

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	05 Sep 2020 16:02:31
User entered 'Day 28'	System	05 Sep 2020 16:02:31

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T12:45:15', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'df3971b1-1800-480f-b801-459293fd6ca6'	System	07 Sep 2020 16:45:20
User entered 'No interference with activity (1)'	System	07 Sep 2020 16:45:20

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T12:45:17', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'df3971b1-1800-480f-b801-459293fd6ca6'	System	07 Sep 2020 16:45:20
User entered '07 Sep 2020 12:45'	System	07 Sep 2020 16:45:20

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 16:02:31

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 16:02:31

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	07 Sep 2020 08:52:32
User entered 'Day 29'	System	07 Sep 2020 08:52:32

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-08T16:39:08', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'af0b636a-5585-4b25-99dd-43d9600deece'	System	08 Sep 2020 20:39:14
User entered 'No interference with activity (1)'	System	08 Sep 2020 20:39:14

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-08T16:39:10', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'af0b636a-5585-4b25-99dd-43d9600deece'	System	08 Sep 2020 20:39:14
User entered '08 Sep 2020 16:39'	System	08 Sep 2020 20:39:14

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 08:52:32

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 08:52:32

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	07 Sep 2020 16:45:20
User entered 'Day 30'	System	07 Sep 2020 16:45:20

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T12:01:05', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7ab3bcb9-2a33-4c3b-b9ec-a34f972cb0ce'	System	09 Sep 2020 16:01:57
User entered 'No interference with activity (1)'	System	09 Sep 2020 16:01:57

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T12:01:08', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7ab3bcb9-2a33-4c3b-b9ec-a34f972cb0ce'	System	09 Sep 2020 16:01:57
User entered '09 Sep 2020 12:01'	System	09 Sep 2020 16:01:57

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 16:45:20

US3372089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 16:45:20

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	16 Aug 2020 20:13:45
User entered 'Day 8'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-18T15:53:27', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8d730f6f-e3ab-416f-a9d3-6a44eef8dc73'	System	18 Aug 2020 19:53:37
User entered 'No interference with activity (1)'	System	18 Aug 2020 19:53:37

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-18T15:53:31', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8d730f6f-e3ab-416f-a9d3-6a44eef8dc73'	System	18 Aug 2020 19:53:37
User entered '18 Aug 2020 15:53'	System	18 Aug 2020 19:53:37

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	17 Aug 2020 20:53:19
User entered 'Day 9'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-19T12:01:49', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'c36acb92-aec8-43f0-9c8c-07fbffcded6e'	System	19 Aug 2020 16:02:11
User entered 'No interference with activity (1)'	System	19 Aug 2020 16:02:11

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-19T12:01:53', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'c36acb92-aec8-43f0-9c8c-07fbffcded6e'	System	19 Aug 2020 16:02:11
User entered '19 Aug 2020 12:01'	System	19 Aug 2020 16:02:11

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	18 Aug 2020 19:53:37
User entered 'Day 10'	System	18 Aug 2020 19:53:37

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-20T16:36:56', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '03543e00-79f5-48de-b6ae-6ed45bb56ce3'	System	20 Aug 2020 20:37:03
User entered 'No interference with activity (1)'	System	20 Aug 2020 20:37:03

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-20T16:36:59', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '03543e00-79f5-48de-b6ae-6ed45bb56ce3'	System	20 Aug 2020 20:37:03
User entered '20 Aug 2020 16:36'	System	20 Aug 2020 20:37:03

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 19:53:37

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 19:53:37

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	19 Aug 2020 16:02:11
User entered 'Day 11'	System	19 Aug 2020 16:02:11

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-21T17:45:10', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'dd38f129-eef9-45dd-bfad-ebb7dd76a86c'	System	21 Aug 2020 21:45:17
User entered 'No interference with activity (1)'	System	21 Aug 2020 21:45:17

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-21T17:45:13', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'dd38f129-eef9-45dd-bfad-ebb7dd76a86c'	System	21 Aug 2020 21:45:17
User entered '21 Aug 2020 17:45'	System	21 Aug 2020 21:45:17

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 16:02:11

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 16:02:11

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	20 Aug 2020 20:37:03
User entered 'Day 12'	System	20 Aug 2020 20:37:03

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-22T12:05:39', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '825e35df-7ee2-4c05-823c-852843a9e1da'	System	22 Aug 2020 16:05:46
User entered 'No interference with activity (1)'	System	22 Aug 2020 16:05:46

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-22T12:05:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '825e35df-7ee2-4c05-823c-852843a9e1da'	System	22 Aug 2020 16:05:46
User entered '22 Aug 2020 12:05'	System	22 Aug 2020 16:05:46

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:37:03

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:37:03

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	21 Aug 2020 21:45:17
User entered 'Day 13'	System	21 Aug 2020 21:45:17

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-23T12:25:49', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e8c716bd-30fe-4be5-acd3-51906e0482f8'	System	23 Aug 2020 16:25:54
User entered 'No interference with activity (1)'	System	23 Aug 2020 16:25:54

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-23T12:25:51', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e8c716bd-30fe-4be5-acd3-51906e0482f8'	System	23 Aug 2020 16:25:54
User entered '23 Aug 2020 12:25'	System	23 Aug 2020 16:25:54

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 21:45:17

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 21:45:17

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	22 Aug 2020 16:05:46
User entered 'Day 14'	System	22 Aug 2020 16:05:46

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-24T16:53:21', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a32985b6-237d-48ed-a0b7-9cacce880827'	System	24 Aug 2020 20:53:30
User entered 'No interference with activity (1)'	System	24 Aug 2020 20:53:30

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-24T16:53:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a32985b6-237d-48ed-a0b7-9cacce880827'	System	24 Aug 2020 20:53:30
User entered '24 Aug 2020 16:53'	System	24 Aug 2020 20:53:30

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 16:05:46

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 16:05:46

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	23 Aug 2020 16:25:54
User entered 'Day 15'	System	23 Aug 2020 16:25:54

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-25T12:52:58', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f1b62ba5-407a-42bd-903e-420af112415c'	System	25 Aug 2020 16:53:06
User entered 'No interference with activity (1)'	System	25 Aug 2020 16:53:06

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-25T12:53:01', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f1b62ba5-407a-42bd-903e-420af112415c'	System	25 Aug 2020 16:53:06
User entered '25 Aug 2020 12:53'	System	25 Aug 2020 16:53:06

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 16:25:54

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 16:25:54

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	24 Aug 2020 20:53:30
User entered 'Day 16'	System	24 Aug 2020 20:53:30

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-26T12:07:22', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b199750d-2e4b-4753-a508-5d3cd8d764c0'	System	26 Aug 2020 16:07:29
User entered 'No interference with activity (1)'	System	26 Aug 2020 16:07:29

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-26T12:07:24', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b199750d-2e4b-4753-a508-5d3cd8d764c0'	System	26 Aug 2020 16:07:29
User entered '26 Aug 2020 12:07'	System	26 Aug 2020 16:07:29

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:53:30

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:53:30

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	25 Aug 2020 16:53:06
User entered 'Day 17'	System	25 Aug 2020 16:53:06

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-27T12:28:36', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '4ffb2ff9-6461-4569-8d5f-9fc855b27e74'	System	27 Aug 2020 16:28:53
User entered 'No interference with activity (1)'	System	27 Aug 2020 16:28:53

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-27T12:28:49', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '4ffb2ff9-6461-4569-8d5f-9fc855b27e74'	System	27 Aug 2020 16:28:53
User entered '27 Aug 2020 12:28'	System	27 Aug 2020 16:28:53

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 16:53:06

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 16:53:06

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	26 Aug 2020 16:07:29
User entered 'Day 18'	System	26 Aug 2020 16:07:29

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-28T12:02:45', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bdee002a-d27a-4bde-9fe9-43d9a8e6f350'	System	28 Aug 2020 16:04:01
User entered 'No interference with activity (1)'	System	28 Aug 2020 16:04:01

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-28T12:02:48', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bdee002a-d27a-4bde-9fe9-43d9a8e6f350'	System	28 Aug 2020 16:04:01
User entered '28 Aug 2020 12:02'	System	28 Aug 2020 16:04:01

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:07:29

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:07:29

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	27 Aug 2020 16:28:53
User entered 'Day 19'	System	27 Aug 2020 16:28:53

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-29T15:31:27', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b3d1d82c-f2b7-426b-b495-f6d574beaddb'	System	29 Aug 2020 19:31:35
User entered 'No interference with activity (1)'	System	29 Aug 2020 19:31:35

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-29T15:31:31', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b3d1d82c-f2b7-426b-b495-f6d574beaddb'	System	29 Aug 2020 19:31:35
User entered '29 Aug 2020 15:31'	System	29 Aug 2020 19:31:35

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:28:53

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:28:53

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	28 Aug 2020 16:04:01
User entered 'Day 20'	System	28 Aug 2020 16:04:01

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-30T12:08:52', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '40b8198f-6fc9-4cee-97f2-9fa01ec4775d'	System	30 Aug 2020 16:09:02
User entered 'No interference with activity (1)'	System	30 Aug 2020 16:09:02

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-30T12:08:55', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '40b8198f-6fc9-4cee-97f2-9fa01ec4775d'	System	30 Aug 2020 16:09:02
User entered '30 Aug 2020 12:08'	System	30 Aug 2020 16:09:02

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:04:01

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:04:01

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	29 Aug 2020 19:31:35
User entered 'Day 21'	System	29 Aug 2020 19:31:35

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-31T14:18:07', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3518ec7b-bb90-4865-a13e-3e533b904145'	System	31 Aug 2020 18:18:14
User entered 'No interference with activity (1)'	System	31 Aug 2020 18:18:14

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-31T14:18:09', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3518ec7b-bb90-4865-a13e-3e533b904145'	System	31 Aug 2020 18:18:14
User entered '31 Aug 2020 14:18'	System	31 Aug 2020 18:18:14

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 19:31:35

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 19:31:35

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	30 Aug 2020 16:09:02
User entered 'Day 22'	System	30 Aug 2020 16:09:02

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-01T16:57:35', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'fb1c5304-2380-4974-b55c-36e484bed791'	System	01 Sep 2020 20:57:42
User entered 'No interference with activity (1)'	System	01 Sep 2020 20:57:42

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-01T16:57:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'fb1c5304-2380-4974-b55c-36e484bed791'	System	01 Sep 2020 20:57:42
User entered '01 Sep 2020 16:57'	System	01 Sep 2020 20:57:42

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 16:09:02

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 16:09:02

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	31 Aug 2020 18:18:14
User entered 'Day 23'	System	31 Aug 2020 18:18:14

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-02T12:06:06', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b5ed43f6-5e40-4b20-87cf-3af0f74654f6'	System	02 Sep 2020 16:06:15
User entered 'No interference with activity (1)'	System	02 Sep 2020 16:06:15

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-02T12:06:10', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b5ed43f6-5e40-4b20-87cf-3af0f74654f6'	System	02 Sep 2020 16:06:15
User entered '02 Sep 2020 12:06'	System	02 Sep 2020 16:06:15

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:18:14

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:18:14

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	01 Sep 2020 20:57:42
User entered 'Day 24'	System	01 Sep 2020 20:57:42

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-03T16:04:35', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd9240004-66fe-45b6-8d21-652fe020d30b'	System	03 Sep 2020 20:04:45
User entered 'No interference with activity (1)'	System	03 Sep 2020 20:04:45

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-03T16:04:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd9240004-66fe-45b6-8d21-652fe020d30b'	System	03 Sep 2020 20:04:45
User entered '03 Sep 2020 16:04'	System	03 Sep 2020 20:04:45

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:57:42

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:57:42

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	02 Sep 2020 16:06:15
User entered 'Day 25'	System	02 Sep 2020 16:06:15

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-04T12:21:01', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9d40a390-4aac-43b1-b115-ab43a1a9e3bc'	System	04 Sep 2020 16:21:07
User entered 'No interference with activity (1)'	System	04 Sep 2020 16:21:07

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-04T12:21:03', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9d40a390-4aac-43b1-b115-ab43a1a9e3bc'	System	04 Sep 2020 16:21:07
User entered '04 Sep 2020 12:21'	System	04 Sep 2020 16:21:07

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:06:15

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:06:15

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	03 Sep 2020 20:04:45
User entered 'Day 26'	System	03 Sep 2020 20:04:45

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-05T12:01:39', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '94811eb8-f88b-41d5-ae7e-651dc1d9ba99'	System	05 Sep 2020 16:02:39
User entered 'No interference with activity (1)'	System	05 Sep 2020 16:02:39

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-05T12:01:41', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '94811eb8-f88b-41d5-ae7e-651dc1d9ba99'	System	05 Sep 2020 16:02:39
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 16:02:39

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 20:04:45

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 20:04:45

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	04 Sep 2020 16:21:07
User entered 'Day 27'	System	04 Sep 2020 16:21:07

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T04:52:10', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8277587c-4f24-4012-b08d-cec9acf4a141'	System	07 Sep 2020 08:52:35
User entered 'No interference with activity (1)'	System	07 Sep 2020 08:52:35

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T04:52:13', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8277587c-4f24-4012-b08d-cec9acf4a141'	System	07 Sep 2020 08:52:35
User entered '07 Sep 2020 04:52'	System	07 Sep 2020 08:52:35

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 16:21:07

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 16:21:07

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	05 Sep 2020 16:02:39
User entered 'Day 28'	System	05 Sep 2020 16:02:39

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T12:45:21', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3190cea7-b613-4753-883f-afec96a41ae0'	System	07 Sep 2020 16:45:27
User entered 'No interference with activity (1)'	System	07 Sep 2020 16:45:27

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T12:45:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3190cea7-b613-4753-883f-afec96a41ae0'	System	07 Sep 2020 16:45:27
User entered '07 Sep 2020 12:45'	System	07 Sep 2020 16:45:27

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 16:02:39

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 16:02:39

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	07 Sep 2020 08:52:35
User entered 'Day 29'	System	07 Sep 2020 08:52:35

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-08T16:39:15', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e586218b-115c-4319-a15a-58fa15eddc5'	System	08 Sep 2020 20:39:21
User entered 'No interference with activity (1)'	System	08 Sep 2020 20:39:21

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-08T16:39:17', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e586218b-115c-4319-a15a-58fa15eddc5'	System	08 Sep 2020 20:39:21
User entered '08 Sep 2020 16:39'	System	08 Sep 2020 20:39:21

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 08:52:35

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 08:52:35

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	07 Sep 2020 16:45:27
User entered 'Day 30'	System	07 Sep 2020 16:45:27

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T12:01:12', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '39e4a0e2-d51f-4ac5-ad4c-6688f037cfeb'	System	09 Sep 2020 16:02:17
User entered 'No interference with activity (1)'	System	09 Sep 2020 16:02:17

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T12:01:14', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '39e4a0e2-d51f-4ac5-ad4c-6688f037cfeb'	System	09 Sep 2020 16:02:17
User entered '09 Sep 2020 12:01'	System	09 Sep 2020 16:02:17

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 16:45:27

US3372089

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 16:45:27

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	16 Aug 2020 20:13:45
User entered 'Day 8'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-18T15:53:40', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '82a99640-b23b-4672-918e-e60114b6e2b0'	System	18 Aug 2020 19:53:49
User entered 'No (N)'	System	18 Aug 2020 19:53:49

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-18T15:53:45', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '82a99640-b23b-4672-918e-e60114b6e2b0'	System	18 Aug 2020 19:53:49
User entered '18 Aug 2020 15:53'	System	18 Aug 2020 19:53:49

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 20:13:45

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	17 Aug 2020 20:53:19
User entered 'Day 9'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-19T12:02:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f8224a09-73e1-4050-b153-738ee890c283'	System	19 Aug 2020 16:02:15
User entered 'No (N)'	System	19 Aug 2020 16:02:15

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-19T12:02:04', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f8224a09-73e1-4050-b153-738ee890c283'	System	19 Aug 2020 16:02:15
User entered '19 Aug 2020 12:02'	System	19 Aug 2020 16:02:15

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:53:19

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	18 Aug 2020 19:53:12
User entered 'Day 10'	System	18 Aug 2020 19:53:12

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-20T16:37:08', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '1475ad2c-128a-4d25-a993-d53c7b250e68'	System	20 Aug 2020 20:37:31
User entered 'Yes (Y)'	System	20 Aug 2020 20:37:31

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-20T16:37:25', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '1475ad2c-128a-4d25-a993-d53c7b250e68'	System	20 Aug 2020 20:37:31
User entered '20 Aug 2020 16:37'	System	20 Aug 2020 20:37:31

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 19:53:12

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 19:53:12

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	19 Aug 2020 16:01:47
User entered 'Day 11'	System	19 Aug 2020 16:01:47

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-21T17:45:21', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '4d9403c5-94c8-49d7-af34-458591a0180a'	System	21 Aug 2020 21:45:28
User entered 'No (N)'	System	21 Aug 2020 21:45:28

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-21T17:45:24', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '4d9403c5-94c8-49d7-af34-458591a0180a'	System	21 Aug 2020 21:45:28
User entered '21 Aug 2020 17:45'	System	21 Aug 2020 21:45:28

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 16:01:47

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 16:01:47

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	20 Aug 2020 20:36:48
User entered 'Day 12'	System	20 Aug 2020 20:36:48

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-22T12:05:51', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd478924e-a43f-469d-b378-32c97da2abfc'	System	22 Aug 2020 16:05:57
User entered 'No (N)'	System	22 Aug 2020 16:05:57

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-22T12:05:53', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd478924e-a43f-469d-b378-32c97da2abfc'	System	22 Aug 2020 16:05:57
User entered '22 Aug 2020 12:05'	System	22 Aug 2020 16:05:57

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:36:48

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:36:48

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	21 Aug 2020 21:44:56
User entered 'Day 13'	System	21 Aug 2020 21:44:56

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-23T12:26:17', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '624728d4-60b9-467d-a72f-6a02df8d7bc7'	System	23 Aug 2020 16:26:25
User entered 'No (N)'	System	23 Aug 2020 16:26:25

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-23T12:26:20', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '624728d4-60b9-467d-a72f-6a02df8d7bc7'	System	23 Aug 2020 16:26:25
User entered '23 Aug 2020 12:26'	System	23 Aug 2020 16:26:25

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 21:44:56

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 21:44:56

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	22 Aug 2020 16:05:28
User entered 'Day 14'	System	22 Aug 2020 16:05:28

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-24T16:53:37', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd39b58d1-ac03-4c55-8d47-34e2ba2d5449'	System	24 Aug 2020 20:53:45
User entered 'No (N)'	System	24 Aug 2020 20:53:45

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-24T16:53:41', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd39b58d1-ac03-4c55-8d47-34e2ba2d5449'	System	24 Aug 2020 20:53:45
User entered '24 Aug 2020 16:53'	System	24 Aug 2020 20:53:45

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 16:05:28

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 16:05:28

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	23 Aug 2020 16:25:47
User entered 'Day 15'	System	23 Aug 2020 16:25:47

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-25T12:53:07', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd3b39b22-d312-4e73-a5eb-691cc48be4e1'	System	25 Aug 2020 16:53:14
User entered 'No (N)'	System	25 Aug 2020 16:53:14

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-25T12:53:10', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd3b39b22-d312-4e73-a5eb-691cc48be4e1'	System	25 Aug 2020 16:53:14
User entered '25 Aug 2020 12:53'	System	25 Aug 2020 16:53:14

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 16:25:47

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 16:25:47

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	24 Aug 2020 20:53:10
User entered 'Day 16'	System	24 Aug 2020 20:53:10

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-26T12:07:32', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '46cf9d29-da74-47db-89e6-1a4ddd261b49'	System	26 Aug 2020 16:07:40
User entered 'No (N)'	System	26 Aug 2020 16:07:40

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-26T12:07:36', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '46cf9d29-da74-47db-89e6-1a4ddd261b49'	System	26 Aug 2020 16:07:40
User entered '26 Aug 2020 12:07'	System	26 Aug 2020 16:07:40

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:53:10

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:53:10

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	25 Aug 2020 16:52:48
User entered 'Day 17'	System	25 Aug 2020 16:52:48

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-27T12:28:54', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ff6d5747-880e-44cb-81ce-41c76c5d8bd7'	System	27 Aug 2020 16:29:01
User entered 'No (N)'	System	27 Aug 2020 16:29:01

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-27T12:28:56', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ff6d5747-880e-44cb-81ce-41c76c5d8bd7'	System	27 Aug 2020 16:29:01
User entered '27 Aug 2020 12:28'	System	27 Aug 2020 16:29:01

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 16:52:48

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 16:52:48

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	26 Aug 2020 16:07:09
User entered 'Day 18'	System	26 Aug 2020 16:07:09

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-28T12:02:52', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '88643525-1ab3-4e1c-9e54-3cb47200e531'	System	28 Aug 2020 16:04:10
User entered 'No (N)'	System	28 Aug 2020 16:04:10

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-28T12:02:54', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '88643525-1ab3-4e1c-9e54-3cb47200e531'	System	28 Aug 2020 16:04:10
User entered '28 Aug 2020 12:02'	System	28 Aug 2020 16:04:10

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:07:09

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:07:09

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	27 Aug 2020 16:28:22
User entered 'Day 19'	System	27 Aug 2020 16:28:22

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-29T15:31:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd3c3401e-c5c7-45ee-8008-23ec76f3a056'	System	29 Aug 2020 19:31:45
User entered 'No (N)'	System	29 Aug 2020 19:31:45

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-29T15:31:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd3c3401e-c5c7-45ee-8008-23ec76f3a056'	System	29 Aug 2020 19:31:45
User entered '29 Aug 2020 15:31'	System	29 Aug 2020 19:31:45

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:28:22

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:28:22

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	28 Aug 2020 16:03:51
User entered 'Day 20'	System	28 Aug 2020 16:03:51

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-30T12:09:02', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '678a6988-a649-4c5b-91b2-b52d4652ae18'	System	30 Aug 2020 16:09:08
User entered 'No (N)'	System	30 Aug 2020 16:09:08

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-30T12:09:05', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '678a6988-a649-4c5b-91b2-b52d4652ae18'	System	30 Aug 2020 16:09:08
User entered '30 Aug 2020 12:09'	System	30 Aug 2020 16:09:08

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:03:51

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:03:51

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	29 Aug 2020 19:31:17
User entered 'Day 21'	System	29 Aug 2020 19:31:17

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-31T14:18:14', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5493d5c0-10ed-42e9-8705-01395705e4ee'	System	31 Aug 2020 18:18:20
User entered 'No (N)'	System	31 Aug 2020 18:18:20

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-08-31T14:18:16', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '5493d5c0-10ed-42e9-8705-01395705e4ee'	System	31 Aug 2020 18:18:20
User entered '31 Aug 2020 14:18'	System	31 Aug 2020 18:18:20

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 19:31:17

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 19:31:17

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	30 Aug 2020 16:08:44
User entered 'Day 22'	System	30 Aug 2020 16:08:44

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-01T16:57:43', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3d7186b5-57fc-4a21-bea4-09bb496d495a'	System	01 Sep 2020 20:57:50
User entered 'No (N)'	System	01 Sep 2020 20:57:50

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-01T16:57:45', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3d7186b5-57fc-4a21-bea4-09bb496d495a'	System	01 Sep 2020 20:57:50
User entered '01 Sep 2020 16:57'	System	01 Sep 2020 20:57:50

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 16:08:44

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 16:08:44

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	31 Aug 2020 18:18:01
User entered 'Day 23'	System	31 Aug 2020 18:18:01

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-02T12:06:15', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '609d5ff8-6eca-4923-a17e-c88b8a554cc7'	System	02 Sep 2020 16:06:28
User entered 'No (N)'	System	02 Sep 2020 16:06:28

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-02T12:06:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '609d5ff8-6eca-4923-a17e-c88b8a554cc7'	System	02 Sep 2020 16:06:28
User entered '02 Sep 2020 12:06'	System	02 Sep 2020 16:06:28

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:18:01

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:18:01

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	01 Sep 2020 20:57:28
User entered 'Day 24'	System	01 Sep 2020 20:57:28

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-03T16:04:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '83e81a7c-9e8a-4634-ba33-7e261237e923'	System	03 Sep 2020 20:04:50
User entered 'No (N)'	System	03 Sep 2020 20:04:50

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-03T16:04:45', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '83e81a7c-9e8a-4634-ba33-7e261237e923'	System	03 Sep 2020 20:04:50
User entered '03 Sep 2020 16:04'	System	03 Sep 2020 20:04:50

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:57:28

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:57:28

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	02 Sep 2020 16:05:58
User entered 'Day 25'	System	02 Sep 2020 16:05:58

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-04T12:21:07', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '128c33ff-2ef1-481e-90d5-64452a3a481a'	System	04 Sep 2020 16:21:13
User entered 'No (N)'	System	04 Sep 2020 16:21:13

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-04T12:21:10', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '128c33ff-2ef1-481e-90d5-64452a3a481a'	System	04 Sep 2020 16:21:13
User entered '04 Sep 2020 12:21'	System	04 Sep 2020 16:21:13

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:05:58

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:05:58

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	03 Sep 2020 20:04:28
User entered 'Day 26'	System	03 Sep 2020 20:04:28

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-05T12:01:45', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '064fcaa6-f858-4b08-9902-dcb287fd2285'	System	05 Sep 2020 16:02:47
User entered 'No (N)'	System	05 Sep 2020 16:02:47

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-05T12:01:48', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '064fcaa6-f858-4b08-9902-dcb287fd2285'	System	05 Sep 2020 16:02:47
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 16:02:47

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 20:04:28

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 20:04:28

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	04 Sep 2020 16:20:52
User entered 'Day 27'	System	04 Sep 2020 16:20:52

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T04:52:18', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ab16856e-9736-4a38-b716-0b3e471dd46f'	System	07 Sep 2020 08:52:47
User entered 'No (N)'	System	07 Sep 2020 08:52:47

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T04:52:21', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ab16856e-9736-4a38-b716-0b3e471dd46f'	System	07 Sep 2020 08:52:47
User entered '07 Sep 2020 04:52'	System	07 Sep 2020 08:52:47

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 16:20:52

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 16:20:52

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	05 Sep 2020 16:02:18
User entered 'Day 28'	System	05 Sep 2020 16:02:18

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T12:45:27', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '39d2e20d-61d5-4d05-a1e0-0a8e504169ad'	System	07 Sep 2020 16:45:33
User entered 'No (N)'	System	07 Sep 2020 16:45:33

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-07T12:45:29', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '39d2e20d-61d5-4d05-a1e0-0a8e504169ad'	System	07 Sep 2020 16:45:33
User entered '07 Sep 2020 12:45'	System	07 Sep 2020 16:45:33

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 16:02:18

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 16:02:18

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	07 Sep 2020 08:52:32
User entered 'Day 29'	System	07 Sep 2020 08:52:32

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-08T16:39:28', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8f1f2432-34de-496f-bb94-f4e9a0dd60c9'	System	08 Sep 2020 20:39:37
User entered 'Yes (Y)'	System	08 Sep 2020 20:39:37

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-08T16:39:33', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8f1f2432-34de-496f-bb94-f4e9a0dd60c9'	System	08 Sep 2020 20:39:37
User entered '08 Sep 2020 16:39'	System	08 Sep 2020 20:39:37

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 08:52:32

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 08:52:32

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	07 Sep 2020 08:52:33
User entered 'Day 29'	System	07 Sep 2020 08:52:33

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-08T16:39:40', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'cc688a7a-656a-43aa-8de1-f178911722da'	System	08 Sep 2020 20:39:50
User entered 'Yes (Y)'	System	08 Sep 2020 20:39:50

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-08T16:39:43', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'cc688a7a-656a-43aa-8de1-f178911722da'	System	08 Sep 2020 20:39:50
User entered '08 Sep 2020 16:39'	System	08 Sep 2020 20:39:50

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 08:52:33

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 08:52:33

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	07 Sep 2020 08:52:35
User entered 'Day 29'	System	07 Sep 2020 08:52:35

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-08T16:39:50', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e0bbc94b-055a-42e8-896d-65aa06bde2ab'	System	08 Sep 2020 20:39:57
User entered 'Yes (Y)'	System	08 Sep 2020 20:39:57

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-08T16:39:53', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e0bbc94b-055a-42e8-896d-65aa06bde2ab'	System	08 Sep 2020 20:39:57
User entered '08 Sep 2020 16:39'	System	08 Sep 2020 20:39:57

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 08:52:35

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 08:52:35

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	07 Sep 2020 16:45:14
User entered 'Day 30'	System	07 Sep 2020 16:45:14

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T12:01:20', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8ff71ec5-4a67-4824-8375-2dfdd13b5646'	System	09 Sep 2020 16:02:31
User entered 'Yes (Y)'	System	09 Sep 2020 16:02:31

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T12:01:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8ff71ec5-4a67-4824-8375-2dfdd13b5646'	System	09 Sep 2020 16:02:31
User entered '09 Sep 2020 12:01'	System	09 Sep 2020 16:02:31

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 16:45:14

US3372089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 16:45:14

US3372089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 17:31:31

US3372089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '18 Aug 2020'	(b) (4) Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 17:31:31

US3372089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 17:31:31

US3372089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 17:31:31
	(b) (4)	

US3372089

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 17:31:36

US3372089

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'I'	System	21 Aug 2020 17:31:36

US3372089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	26 Aug 2020 16:27:15

US3372089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '25 Aug 2020'	(b) (4) Alexandra Arango (b) (4) (b) (4)	26 Aug 2020 16:27:15

US3372089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	26 Aug 2020 16:27:15

US3372089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Alexandra Arango (b) (4)	26 Aug 2020 16:27:15

US3372089

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	26 Aug 2020 16:27:17

US3372089

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'I'	System	26 Aug 2020 16:27:17

US3372089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 19:12:15

US3372089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '1 Sep 2020'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 19:12:15

US3372089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 19:12:15

US3372089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	03 Sep 2020 19:12:15

US3372089

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 19:12:20

US3372089

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'I'	System	03 Sep 2020 19:12:20

US3372089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:38:42

US3372089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:38:42

US3372089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:38:42

US3372089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'VISIT2'	System	09 Sep 2020 17:38:42

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '09 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '14:26'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered '09 Sep 2020 14:26'	System	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '36.4' C	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '63'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'bpm'	System	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '18'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'breaths/min'	System	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '149'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'mmHg'	System	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '87'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'mmHg'	System	15 Sep 2020 19:48:40

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '09 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '15:59'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered '09 Sep 2020 15:59'	System	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '36.3' C	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '64'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'bpm'	System	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '17'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'breaths/min'	System	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 10:26:33
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:19
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	15 Sep 2020 19:55:12
User entered '158'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'mmHg'	System	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '93'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'mmHg'	System	15 Sep 2020 19:55:12

US3372089

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 19:55:29

US3372089

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '09 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:29

US3372089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:28:45

US3372089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:28:45

US3372089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:28:45

US3372089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 19:28:45

US3372089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:28:45

US3372089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '15:19'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:28:45

US3372089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered '9 Sep 2020 15:19'	System	09 Sep 2020 19:28:45

US3372089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:28:45

US3372089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'ONCE'	System	09 Sep 2020 19:28:45

US3372089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 19:28:45

US3372089

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 19:55:44

US3372089

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '09 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:44

US3372089

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '14:45'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:44

US3372089

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered '09 Sep 2020 14:45'	System	15 Sep 2020 19:55:44

US3372089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:12:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '09 Sep 2020'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 19:55:58

US3372089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:58

US3372089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 19:55:58

US3372089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '14:42'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:58

US3372089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered '09 Sep 2020 14:42'	System	15 Sep 2020 19:55:58

US3372089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:58

US3372089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	15 Sep 2020 19:55:58

US3372089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Sep 2020 19:55:58

US3372089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered empty.	System	15 Sep 2020 19:55:58

US3372089

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	15 Sep 2020 18:48:54

US3372089

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered '1'	System	15 Sep 2020 18:48:54

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T15:59:51', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '78ce2b14-c3c0-4c94-a7ef-e69e7509c015'	System	09 Sep 2020 20:00:20
User entered 'Yes (Y)'	System	09 Sep 2020 20:00:20

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T15:59:59', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '78ce2b14-c3c0-4c94-a7ef-e69e7509c015'	System	09 Sep 2020 20:00:20
User entered '97.3'	System	09 Sep 2020 20:00:20

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:00:08', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '78ce2b14-c3c0-4c94-a7ef-e69e7509c015'	System	09 Sep 2020 20:00:20
User entered 'No (N)'	System	09 Sep 2020 20:00:20

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:00:15', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '78ce2b14-c3c0-4c94-a7ef-e69e7509c015'	System	09 Sep 2020 20:00:20
User entered '09 Sep 2020 16:00'	System	09 Sep 2020 20:00:20

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 15:39'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 18:09'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:05:28', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b0f9aac6-7eec-44af-a97b-0d4f931d98f3'	System	09 Sep 2020 23:05:56
User entered 'Yes (Y)'	System	09 Sep 2020 23:05:56

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:05:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b0f9aac6-7eec-44af-a97b-0d4f931d98f3'	System	09 Sep 2020 23:05:56
User entered '97.5'	System	09 Sep 2020 23:05:56

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:05:46', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b0f9aac6-7eec-44af-a97b-0d4f931d98f3'	System	09 Sep 2020 23:05:56
User entered 'No (N)'	System	09 Sep 2020 23:05:56

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:05:51', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b0f9aac6-7eec-44af-a97b-0d4f931d98f3'	System	09 Sep 2020 23:05:56
User entered '09 Sep 2020 19:05'	System	09 Sep 2020 23:05:56

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 19:04'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 2'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:20:34', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a469747b-07d2-4560-baf1-d552e12babfe'	System	10 Sep 2020 22:20:59
User entered 'Yes (Y)'	System	10 Sep 2020 22:20:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:20:45', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a469747b-07d2-4560-baf1-d552e12babfe'	System	10 Sep 2020 22:20:59
User entered '97.5'	System	10 Sep 2020 22:20:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:20:50', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a469747b-07d2-4560-baf1-d552e12babfe'	System	10 Sep 2020 22:20:59
User entered 'No (N)'	System	10 Sep 2020 22:20:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:20:54', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a469747b-07d2-4560-baf1-d552e12babfe'	System	10 Sep 2020 22:20:59
User entered '10 Sep 2020 18:20'	System	10 Sep 2020 22:20:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 3'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:51:43', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ef5f8145-b975-4ece-b339-87977289e13c'	System	11 Sep 2020 23:52:16
User entered 'Yes (Y)'	System	11 Sep 2020 23:52:16

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:51:59', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ef5f8145-b975-4ece-b339-87977289e13c'	System	11 Sep 2020 23:52:16
User entered '95.6'	System	11 Sep 2020 23:52:16

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:05', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ef5f8145-b975-4ece-b339-87977289e13c'	System	11 Sep 2020 23:52:16
User entered 'No (N)'	System	11 Sep 2020 23:52:16

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:09', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'ef5f8145-b975-4ece-b339-87977289e13c'	System	11 Sep 2020 23:52:16
User entered '11 Sep 2020 19:52'	System	11 Sep 2020 23:52:16

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 4'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:30:44', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bab9c762-ffaa-4ff3-94c7-be1740a7d7b5'	System	12 Sep 2020 19:31:08
User entered 'Yes (Y)'	System	12 Sep 2020 19:31:08

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:30:52', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bab9c762-ffaa-4ff3-94c7-be1740a7d7b5'	System	12 Sep 2020 19:31:08
User entered '98.4'	System	12 Sep 2020 19:31:08

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:30:59', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bab9c762-ffaa-4ff3-94c7-be1740a7d7b5'	System	12 Sep 2020 19:31:08
User entered 'No (N)'	System	12 Sep 2020 19:31:08

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:31:04', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'bab9c762-ffaa-4ff3-94c7-be1740a7d7b5'	System	12 Sep 2020 19:31:08
User entered '12 Sep 2020 15:31'	System	12 Sep 2020 19:31:08

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 5'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:41:16', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b9120acb-c4d4-4aa2-b3cd-724c2c144f58'	System	13 Sep 2020 20:41:39
User entered 'Yes (Y)'	System	13 Sep 2020 20:41:39

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:41:22', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b9120acb-c4d4-4aa2-b3cd-724c2c144f58'	System	13 Sep 2020 20:41:39
User entered '98.3'	System	13 Sep 2020 20:41:39

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:41:29', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b9120acb-c4d4-4aa2-b3cd-724c2c144f58'	System	13 Sep 2020 20:41:39
User entered 'No (N)'	System	13 Sep 2020 20:41:39

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:41:35', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b9120acb-c4d4-4aa2-b3cd-724c2c144f58'	System	13 Sep 2020 20:41:39
User entered '13 Sep 2020 16:41'	System	13 Sep 2020 20:41:39

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 6'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:43:29', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9bfee177-66fe-4166-8cd8-6796bbf6e19f'	System	14 Sep 2020 20:44:02
User entered 'Yes (Y)'	System	14 Sep 2020 20:44:02

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:43:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9bfee177-66fe-4166-8cd8-6796bbf6e19f'	System	14 Sep 2020 20:44:02
User entered '98.9'	System	14 Sep 2020 20:44:02

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:43:46', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9bfee177-66fe-4166-8cd8-6796bbf6e19f'	System	14 Sep 2020 20:44:02
User entered 'No (N)'	System	14 Sep 2020 20:44:02

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:43:55', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9bfee177-66fe-4166-8cd8-6796bbf6e19f'	System	14 Sep 2020 20:44:02
User entered '14 Sep 2020 16:43'	System	14 Sep 2020 20:44:02

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 7'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:14:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8365dbd1-1fb8-403e-8230-91425597d2b5'	System	15 Sep 2020 19:14:59
User entered 'Yes (Y)'	System	15 Sep 2020 19:14:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:14:46', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8365dbd1-1fb8-403e-8230-91425597d2b5'	System	15 Sep 2020 19:14:59
User entered '97.9'	System	15 Sep 2020 19:14:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:14:51', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8365dbd1-1fb8-403e-8230-91425597d2b5'	System	15 Sep 2020 19:14:59
User entered 'No (N)'	System	15 Sep 2020 19:14:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:14:55', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '8365dbd1-1fb8-403e-8230-91425597d2b5'	System	15 Sep 2020 19:14:59
User entered '15 Sep 2020 15:14'	System	15 Sep 2020 19:14:59

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:00:22', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a8d9bb43-92c3-4ea0-8d6d-01c01a5649db'	System	09 Sep 2020 20:00:47
User entered 'None (1)'	System	09 Sep 2020 20:00:47

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:00:29', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a8d9bb43-92c3-4ea0-8d6d-01c01a5649db'	System	09 Sep 2020 20:00:47
User entered 'No (N)'	System	09 Sep 2020 20:00:47

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:00:32', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a8d9bb43-92c3-4ea0-8d6d-01c01a5649db'	System	09 Sep 2020 20:00:47
User entered 'No (N)'	System	09 Sep 2020 20:00:47

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:00:37', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a8d9bb43-92c3-4ea0-8d6d-01c01a5649db'	System	09 Sep 2020 20:00:47
User entered 'None (1)'	System	09 Sep 2020 20:00:47

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:00:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a8d9bb43-92c3-4ea0-8d6d-01c01a5649db'	System	09 Sep 2020 20:00:47
User entered '09 Sep 2020 16:00'	System	09 Sep 2020 20:00:47

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 15:39'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 18:09'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:05:58', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a97e6779-b47c-429f-abcf-dec87b3b6b3a'	System	09 Sep 2020 23:06:21
User entered 'None (1)'	System	09 Sep 2020 23:06:21

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:06:03', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a97e6779-b47c-429f-abcf-dec87b3b6b3a'	System	09 Sep 2020 23:06:21
User entered 'No (N)'	System	09 Sep 2020 23:06:21

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:06:07', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a97e6779-b47c-429f-abcf-dec87b3b6b3a'	System	09 Sep 2020 23:06:21
User entered 'No (N)'	System	09 Sep 2020 23:06:21

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:06:13', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a97e6779-b47c-429f-abcf-dec87b3b6b3a'	System	09 Sep 2020 23:06:21
User entered 'None (1)'	System	09 Sep 2020 23:06:21

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:06:17', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a97e6779-b47c-429f-abcf-dec87b3b6b3a'	System	09 Sep 2020 23:06:21
User entered '09 Sep 2020 19:06'	System	09 Sep 2020 23:06:21

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 19:04'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 2'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:21:01', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e2e64543-a475-4919-8bfa-513c3e704481'	System	10 Sep 2020 22:21:28
User entered 'None (1)'	System	10 Sep 2020 22:21:28

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:21:06', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e2e64543-a475-4919-8bfa-513c3e704481'	System	10 Sep 2020 22:21:28
User entered 'No (N)'	System	10 Sep 2020 22:21:28

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:21:10', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e2e64543-a475-4919-8bfa-513c3e704481'	System	10 Sep 2020 22:21:28
User entered 'No (N)'	System	10 Sep 2020 22:21:28

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:21:18', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e2e64543-a475-4919-8bfa-513c3e704481'	System	10 Sep 2020 22:21:28
User entered 'None (1)'	System	10 Sep 2020 22:21:28

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:21:25', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e2e64543-a475-4919-8bfa-513c3e704481'	System	10 Sep 2020 22:21:28
User entered '10 Sep 2020 18:21'	System	10 Sep 2020 22:21:28

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 3'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:15', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f3e09148-06f7-412e-9801-95f07c665baf'	System	11 Sep 2020 23:52:37
User entered 'None (1)'	System	11 Sep 2020 23:52:37

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:19', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f3e09148-06f7-412e-9801-95f07c665baf'	System	11 Sep 2020 23:52:37
User entered 'No (N)'	System	11 Sep 2020 23:52:37

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f3e09148-06f7-412e-9801-95f07c665baf'	System	11 Sep 2020 23:52:37
User entered 'No (N)'	System	11 Sep 2020 23:52:37

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:28', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f3e09148-06f7-412e-9801-95f07c665baf'	System	11 Sep 2020 23:52:37
User entered 'None (1)'	System	11 Sep 2020 23:52:37

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:31', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f3e09148-06f7-412e-9801-95f07c665baf'	System	11 Sep 2020 23:52:37
User entered '11 Sep 2020 19:52'	System	11 Sep 2020 23:52:37

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 4'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:31:10', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b9beea70-7d0c-47ff-b56c-df772b60d8c5'	System	12 Sep 2020 19:31:37
User entered 'None (1)'	System	12 Sep 2020 19:31:37

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:31:15', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b9beea70-7d0c-47ff-b56c-df772b60d8c5'	System	12 Sep 2020 19:31:37
User entered 'No (N)'	System	12 Sep 2020 19:31:37

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:31:19', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b9beea70-7d0c-47ff-b56c-df772b60d8c5'	System	12 Sep 2020 19:31:37
User entered 'No (N)'	System	12 Sep 2020 19:31:37

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:31:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b9beea70-7d0c-47ff-b56c-df772b60d8c5'	System	12 Sep 2020 19:31:37
User entered 'None (1)'	System	12 Sep 2020 19:31:37

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:31:31', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b9beea70-7d0c-47ff-b56c-df772b60d8c5'	System	12 Sep 2020 19:31:37
User entered '12 Sep 2020 15:31'	System	12 Sep 2020 19:31:37

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 5'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:38:41', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0595f52e-1557-42c8-9e72-654df7976a07'	System	13 Sep 2020 20:39:05
User entered 'None (1)'	System	13 Sep 2020 20:39:05

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:38:45', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0595f52e-1557-42c8-9e72-654df7976a07'	System	13 Sep 2020 20:39:05
User entered 'No (N)'	System	13 Sep 2020 20:39:05

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:38:49', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0595f52e-1557-42c8-9e72-654df7976a07'	System	13 Sep 2020 20:39:05
User entered 'No (N)'	System	13 Sep 2020 20:39:05

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:38:54', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0595f52e-1557-42c8-9e72-654df7976a07'	System	13 Sep 2020 20:39:05
User entered 'None (1)'	System	13 Sep 2020 20:39:05

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:39:02', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0595f52e-1557-42c8-9e72-654df7976a07'	System	13 Sep 2020 20:39:05
User entered '13 Sep 2020 16:39'	System	13 Sep 2020 20:39:05

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 6'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:44:03', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f6a4d483-8967-4b08-b64c-f075ee9e4f44'	System	14 Sep 2020 20:44:29
User entered 'None (1)'	System	14 Sep 2020 20:44:29

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:44:07', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f6a4d483-8967-4b08-b64c-f075ee9e4f44'	System	14 Sep 2020 20:44:29
User entered 'No (N)'	System	14 Sep 2020 20:44:29

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:44:11', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f6a4d483-8967-4b08-b64c-f075ee9e4f44'	System	14 Sep 2020 20:44:29
User entered 'No (N)'	System	14 Sep 2020 20:44:29

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:44:20', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f6a4d483-8967-4b08-b64c-f075ee9e4f44'	System	14 Sep 2020 20:44:29
User entered 'None (1)'	System	14 Sep 2020 20:44:29

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:44:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'f6a4d483-8967-4b08-b64c-f075ee9e4f44'	System	14 Sep 2020 20:44:29
User entered '14 Sep 2020 16:44'	System	14 Sep 2020 20:44:29

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 7'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:15:05', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '4562c40e-561e-4b0f-84c5-f47c1fcf1b1e'	System	15 Sep 2020 19:15:25
User entered 'None (1)'	System	15 Sep 2020 19:15:25

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:15:09', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '4562c40e-561e-4b0f-84c5-f47c1fcf1b1e'	System	15 Sep 2020 19:15:25
User entered 'No (N)'	System	15 Sep 2020 19:15:25

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:15:14', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '4562c40e-561e-4b0f-84c5-f47c1fcf1b1e'	System	15 Sep 2020 19:15:25
User entered 'No (N)'	System	15 Sep 2020 19:15:25

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:15:18', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '4562c40e-561e-4b0f-84c5-f47c1fcf1b1e'	System	15 Sep 2020 19:15:25
User entered 'None (1)'	System	15 Sep 2020 19:15:25

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:15:21', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '4562c40e-561e-4b0f-84c5-f47c1fcf1b1e'	System	15 Sep 2020 19:15:25
User entered '15 Sep 2020 15:15'	System	15 Sep 2020 19:15:25

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:00:49', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2623d25f-59de-4ce5-b4f9-503037c359b2'	System	09 Sep 2020 20:01:18
User entered 'None (0)'	System	09 Sep 2020 20:01:18

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:00:52', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2623d25f-59de-4ce5-b4f9-503037c359b2'	System	09 Sep 2020 20:01:18
User entered 'None (0)'	System	09 Sep 2020 20:01:18

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:00:56', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2623d25f-59de-4ce5-b4f9-503037c359b2'	System	09 Sep 2020 20:01:18
User entered 'None (0)'	System	09 Sep 2020 20:01:18

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:00:59', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2623d25f-59de-4ce5-b4f9-503037c359b2'	System	09 Sep 2020 20:01:18
User entered 'None (0)'	System	09 Sep 2020 20:01:18

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:01:02', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2623d25f-59de-4ce5-b4f9-503037c359b2'	System	09 Sep 2020 20:01:18
User entered 'None (0)'	System	09 Sep 2020 20:01:18

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:01:06', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2623d25f-59de-4ce5-b4f9-503037c359b2'	System	09 Sep 2020 20:01:18
User entered 'None (0)'	System	09 Sep 2020 20:01:18

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:01:10', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2623d25f-59de-4ce5-b4f9-503037c359b2'	System	09 Sep 2020 20:01:18
User entered 'No (N)'	System	09 Sep 2020 20:01:18

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T16:01:13', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2623d25f-59de-4ce5-b4f9-503037c359b2'	System	09 Sep 2020 20:01:18
User entered '09 Sep 2020 16:01'	System	09 Sep 2020 20:01:18

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 15:39'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 18:09'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:06:28', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '39a0ac4d-d9b8-4118-bc68-1942c2a312a9'	System	09 Sep 2020 23:07:05
User entered 'None (0)'	System	09 Sep 2020 23:07:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:06:32', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '39a0ac4d-d9b8-4118-bc68-1942c2a312a9'	System	09 Sep 2020 23:07:05
User entered 'None (0)'	System	09 Sep 2020 23:07:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:06:35', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '39a0ac4d-d9b8-4118-bc68-1942c2a312a9'	System	09 Sep 2020 23:07:05
User entered 'None (0)'	System	09 Sep 2020 23:07:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:06:40', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '39a0ac4d-d9b8-4118-bc68-1942c2a312a9' User entered 'None (0)'	System	09 Sep 2020 23:07:05
	System	09 Sep 2020 23:07:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:06:44', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '39a0ac4d-d9b8-4118-bc68-1942c2a312a9' User entered 'None (0)'	System	09 Sep 2020 23:07:05
	System	09 Sep 2020 23:07:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:06:48', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '39a0ac4d-d9b8-4118-bc68-1942c2a312a9'	System	09 Sep 2020 23:07:05
User entered 'None (0)'	System	09 Sep 2020 23:07:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:06:57', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '39a0ac4d-d9b8-4118-bc68-1942c2a312a9'	System	09 Sep 2020 23:07:05
User entered 'No (N)'	System	09 Sep 2020 23:07:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-09T19:07:01', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '39a0ac4d-d9b8-4118-bc68-1942c2a312a9' User entered '09 Sep 2020 19:07'	System	09 Sep 2020 23:07:05
	System	09 Sep 2020 23:07:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '09 Sep 2020 19:04'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 2'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:21:32', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0eb2bce1-0a4b-4986-be6c-8f78cc0407c2'	System	10 Sep 2020 22:22:03
User entered 'None (0)'	System	10 Sep 2020 22:22:03

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:21:35', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0eb2bce1-0a4b-4986-be6c-8f78cc0407c2'	System	10 Sep 2020 22:22:03
User entered 'None (0)'	System	10 Sep 2020 22:22:03

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:21:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0eb2bce1-0a4b-4986-be6c-8f78cc0407c2'	System	10 Sep 2020 22:22:03
User entered 'None (0)'	System	10 Sep 2020 22:22:03

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:21:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0eb2bce1-0a4b-4986-be6c-8f78cc0407c2'	System	10 Sep 2020 22:22:03
User entered 'None (0)'	System	10 Sep 2020 22:22:03

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:21:45', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0eb2bce1-0a4b-4986-be6c-8f78cc0407c2'	System	10 Sep 2020 22:22:03
User entered 'None (0)'	System	10 Sep 2020 22:22:03

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:21:49', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0eb2bce1-0a4b-4986-be6c-8f78cc0407c2'	System	10 Sep 2020 22:22:03
User entered 'None (0)'	System	10 Sep 2020 22:22:03

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:21:55', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0eb2bce1-0a4b-4986-be6c-8f78cc0407c2'	System	10 Sep 2020 22:22:03
User entered 'No (N)'	System	10 Sep 2020 22:22:03

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-10T18:21:58', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0eb2bce1-0a4b-4986-be6c-8f78cc0407c2'	System	10 Sep 2020 22:22:03
User entered '10 Sep 2020 18:21'	System	10 Sep 2020 22:22:03

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 3'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:36', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b600fd84-e982-4c3b-b0da-b39f707b5475'	System	11 Sep 2020 23:53:06
User entered 'None (0)'	System	11 Sep 2020 23:53:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:39', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b600fd84-e982-4c3b-b0da-b39f707b5475'	System	11 Sep 2020 23:53:06
User entered 'None (0)'	System	11 Sep 2020 23:53:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b600fd84-e982-4c3b-b0da-b39f707b5475'	System	11 Sep 2020 23:53:06
User entered 'None (0)'	System	11 Sep 2020 23:53:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:45', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b600fd84-e982-4c3b-b0da-b39f707b5475'	System	11 Sep 2020 23:53:06
User entered 'None (0)'	System	11 Sep 2020 23:53:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:48', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b600fd84-e982-4c3b-b0da-b39f707b5475'	System	11 Sep 2020 23:53:06
User entered 'None (0)'	System	11 Sep 2020 23:53:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:52', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b600fd84-e982-4c3b-b0da-b39f707b5475'	System	11 Sep 2020 23:53:06
User entered 'None (0)'	System	11 Sep 2020 23:53:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:52:56', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b600fd84-e982-4c3b-b0da-b39f707b5475'	System	11 Sep 2020 23:53:06
User entered 'No (N)'	System	11 Sep 2020 23:53:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-11T19:53:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b600fd84-e982-4c3b-b0da-b39f707b5475'	System	11 Sep 2020 23:53:06
User entered '11 Sep 2020 19:53'	System	11 Sep 2020 23:53:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 4'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:31:36', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0ecf5a44-a65b-4f01-87bb-9dd54a506348'	System	12 Sep 2020 19:32:06
User entered 'None (0)'	System	12 Sep 2020 19:32:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:31:40', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0ecf5a44-a65b-4f01-87bb-9dd54a506348'	System	12 Sep 2020 19:32:06
User entered 'None (0)'	System	12 Sep 2020 19:32:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:31:43', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0ecf5a44-a65b-4f01-87bb-9dd54a506348'	System	12 Sep 2020 19:32:06
User entered 'None (0)'	System	12 Sep 2020 19:32:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:31:46', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0ecf5a44-a65b-4f01-87bb-9dd54a506348'	System	12 Sep 2020 19:32:06
User entered 'None (0)'	System	12 Sep 2020 19:32:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:31:50', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0ecf5a44-a65b-4f01-87bb-9dd54a506348'	System	12 Sep 2020 19:32:06
User entered 'None (0)'	System	12 Sep 2020 19:32:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:31:55', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0ecf5a44-a65b-4f01-87bb-9dd54a506348'	System	12 Sep 2020 19:32:06
User entered 'None (0)'	System	12 Sep 2020 19:32:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:32:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0ecf5a44-a65b-4f01-87bb-9dd54a506348'	System	12 Sep 2020 19:32:06
User entered 'No (N)'	System	12 Sep 2020 19:32:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-12T15:32:03', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0ecf5a44-a65b-4f01-87bb-9dd54a506348'	System	12 Sep 2020 19:32:06
User entered '12 Sep 2020 15:32'	System	12 Sep 2020 19:32:06

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 5'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:39:08', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '15df89a5-63bb-4158-b8fc-c81576653751'	System	13 Sep 2020 20:39:46
User entered 'None (0)'	System	13 Sep 2020 20:39:46

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:39:11', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '15df89a5-63bb-4158-b8fc-c81576653751'	System	13 Sep 2020 20:39:46
User entered 'None (0)'	System	13 Sep 2020 20:39:46

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:39:15', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '15df89a5-63bb-4158-b8fc-c81576653751'	System	13 Sep 2020 20:39:46
User entered 'None (0)'	System	13 Sep 2020 20:39:46

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:39:18', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '15df89a5-63bb-4158-b8fc-c81576653751'	System	13 Sep 2020 20:39:46
User entered 'None (0)'	System	13 Sep 2020 20:39:46

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:39:20', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '15df89a5-63bb-4158-b8fc-c81576653751'	System	13 Sep 2020 20:39:46
User entered 'None (0)'	System	13 Sep 2020 20:39:46

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:39:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '15df89a5-63bb-4158-b8fc-c81576653751'	System	13 Sep 2020 20:39:46
User entered 'None (0)'	System	13 Sep 2020 20:39:46

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:39:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '15df89a5-63bb-4158-b8fc-c81576653751'	System	13 Sep 2020 20:39:46
User entered 'No (N)'	System	13 Sep 2020 20:39:46

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-13T16:39:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '15df89a5-63bb-4158-b8fc-c81576653751'	System	13 Sep 2020 20:39:46
User entered '13 Sep 2020 16:39'	System	13 Sep 2020 20:39:46

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 6'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:44:31', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2acea5fe-6d09-46fc-9538-013b08ed8b2c'	System	14 Sep 2020 20:45:05
User entered 'None (0)'	System	14 Sep 2020 20:45:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:44:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2acea5fe-6d09-46fc-9538-013b08ed8b2c'	System	14 Sep 2020 20:45:05
User entered 'None (0)'	System	14 Sep 2020 20:45:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:44:41', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2acea5fe-6d09-46fc-9538-013b08ed8b2c'	System	14 Sep 2020 20:45:05
User entered 'None (0)'	System	14 Sep 2020 20:45:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:44:45', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2acea5fe-6d09-46fc-9538-013b08ed8b2c'	System	14 Sep 2020 20:45:05
User entered 'None (0)'	System	14 Sep 2020 20:45:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:44:48', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2acea5fe-6d09-46fc-9538-013b08ed8b2c'	System	14 Sep 2020 20:45:05
User entered 'None (0)'	System	14 Sep 2020 20:45:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:44:52', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2acea5fe-6d09-46fc-9538-013b08ed8b2c'	System	14 Sep 2020 20:45:05
User entered 'None (0)'	System	14 Sep 2020 20:45:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:44:56', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2acea5fe-6d09-46fc-9538-013b08ed8b2c'	System	14 Sep 2020 20:45:05
User entered 'No (N)'	System	14 Sep 2020 20:45:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-14T16:44:59', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '2acea5fe-6d09-46fc-9538-013b08ed8b2c'	System	14 Sep 2020 20:45:05
User entered '14 Sep 2020 16:44'	System	14 Sep 2020 20:45:05

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	09 Sep 2020 19:28:45
User entered 'Day 7'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:15:29', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '85080dfa-6ac4-4db0-ac32-96a3e27c36aa'	System	15 Sep 2020 19:16:00
User entered 'None (0)'	System	15 Sep 2020 19:16:00

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:15:33', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '85080dfa-6ac4-4db0-ac32-96a3e27c36aa'	System	15 Sep 2020 19:16:00
User entered 'None (0)'	System	15 Sep 2020 19:16:00

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:15:36', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '85080dfa-6ac4-4db0-ac32-96a3e27c36aa'	System	15 Sep 2020 19:16:00
User entered 'None (0)'	System	15 Sep 2020 19:16:00

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:15:40', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '85080dfa-6ac4-4db0-ac32-96a3e27c36aa'	System	15 Sep 2020 19:16:00
User entered 'None (0)'	System	15 Sep 2020 19:16:00

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:15:43', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '85080dfa-6ac4-4db0-ac32-96a3e27c36aa'	System	15 Sep 2020 19:16:00
User entered 'None (0)'	System	15 Sep 2020 19:16:00

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:15:47', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '85080dfa-6ac4-4db0-ac32-96a3e27c36aa'	System	15 Sep 2020 19:16:00
User entered 'None (0)'	System	15 Sep 2020 19:16:00

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:15:52', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '85080dfa-6ac4-4db0-ac32-96a3e27c36aa'	System	15 Sep 2020 19:16:00
User entered 'No (N)'	System	15 Sep 2020 19:16:00

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-09-15T15:15:55', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '85080dfa-6ac4-4db0-ac32-96a3e27c36aa'	System	15 Sep 2020 19:16:00
User entered '15 Sep 2020 15:15'	System	15 Sep 2020 19:16:00

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 19:28:45

US3372089

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:12:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 19:28:45

US3372089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	15 Sep 2020 18:49:04

US3372089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 09:56:48
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Phone visit completed within protocol per protocol.' (Site from System).	Alexandra Arango (b) (4) (b) (4)	15 Sep 2020 18:49:07
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Sep 2020 18:49:04
User entered '15 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	15 Sep 2020 18:49:04

US3372089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	15 Sep 2020 18:49:04

US3372089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	15 Sep 2020 18:49:04

US3372089

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	15 Sep 2020 18:49:13

US3372089

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'I'	System	15 Sep 2020 18:49:13

US3372089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	29 Sep 2020 20:27:22

US3372089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '23 Sep 2020'	(b) (4) Alexandra Arango (b) (4)	29 Sep 2020 20:27:22

US3372089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	29 Sep 2020 20:27:22

US3372089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	29 Sep 2020 20:27:22

US3372089

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	29 Sep 2020 20:27:26

US3372089

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'I'	System	29 Sep 2020 20:27:26

US3372089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	29 Sep 2020 20:28:58

US3372089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 11:48:28
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Phone visit completed within window per protocol' (Site from System).	Alexandra Arango (b) (4) (b) (4)	29 Sep 2020 20:30:02
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Sep 2020 20:28:58
User entered '29 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	29 Sep 2020 20:28:58

US3372089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	29 Sep 2020 20:28:58

US3372089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	29 Sep 2020 20:28:58

US3372089

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	29 Sep 2020 20:30:08

US3372089

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'I'	System	29 Sep 2020 20:30:08

US3372089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:02:10

US3372089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4)	15 Oct 2020 20:35:08
User entered '6 Oct 2020'	Peter Jacob (b) (4)	06 Oct 2020 15:02:10
	(b) (4)	
	(b) (4), (b) (6)	

US3372089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:02:10

US3372089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'VISIT3'	System	06 Oct 2020 15:02:10

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered empty.	System	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4)	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered empty.	System	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered empty.	System	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered empty.	System	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4)	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered empty.	System	12 Oct 2020 21:09:48

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18

US3372089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18

US3372089

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	15 Oct 2020 20:35:18
User entered 'Yes (Y)'	(b) (4)	
	Peter Jacob (b) (4)	12 Oct 2020 21:17:04
	(b) (4)	

US3372089

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty; reason for change Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	15 Oct 2020 20:35:18
User entered '06 Oct 2020'	(b) (4)	
	Peter Jacob (b) (4)	12 Oct 2020 21:17:04
	(b) (4)	

US3372089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	12 Oct 2020 21:17:11

US3372089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '06 Oct 2020'	(b) (4) Peter Jacob (b) (4)	12 Oct 2020 21:17:11

US3372089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '10:36'	(b) (4) Peter Jacob (b) (4) (b) (4)	12 Oct 2020 21:17:11

US3372089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered '06 Oct 2020 10:36'	System	12 Oct 2020 21:17:11

US3372089

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	12 Oct 2020 21:17:14

US3372089

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'I'	System	12 Oct 2020 21:17:14

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 64'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-10-12T16:09:28', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b815d59c-53a4-488d-ba16-ef1f3e0d2caf'	System	12 Oct 2020 20:09:47
User entered 'No (N)'	System	12 Oct 2020 20:09:47

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-10-12T16:09:33', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b815d59c-53a4-488d-ba16-ef1f3e0d2caf'	System	12 Oct 2020 20:09:47
User entered 'No (N)'	System	12 Oct 2020 20:09:47

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-10-12T16:09:40', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'b815d59c-53a4-488d-ba16-ef1f3e0d2caf'	System	12 Oct 2020 20:09:47
User entered '12 Oct 2020 16:09:40'	System	12 Oct 2020 20:09:47

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 71'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-10-18T03:48:48', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '36e2cb53-7036-4577-bc54-5dc11663ee1e'	System	18 Oct 2020 07:49:20
User entered 'No (N)'	System	18 Oct 2020 07:49:20

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-10-18T03:48:57', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '36e2cb53-7036-4577-bc54-5dc11663ee1e'	System	18 Oct 2020 07:49:20
User entered 'No (N)'	System	18 Oct 2020 07:49:20

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-10-18T03:49:16', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '36e2cb53-7036-4577-bc54-5dc11663ee1e' User entered '18 Oct 2020 03:49:16'	System	18 Oct 2020 07:49:20
	System	18 Oct 2020 07:49:20

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 78'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-10-25T03:05:52', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '6440bfdf-aab5-47d3-aba3-060a5ea647ac'	System	25 Oct 2020 07:06:11
User entered 'No (N)'	System	25 Oct 2020 07:06:11

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-10-25T03:06:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '6440bfdf-aab5-47d3-aba3-060a5ea647ac'	System	25 Oct 2020 07:06:11
User entered 'No (N)'	System	25 Oct 2020 07:06:11

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-10-25T03:06:08', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '6440bfdf-aab5-47d3-aba3-060a5ea647ac'	System	25 Oct 2020 07:06:11
User entered '25 Oct 2020 03:06:08'	System	25 Oct 2020 07:06:11

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 92'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38
Data entry locked.	System	11 Aug 2020 20:17:03
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:03:38
Data entry locked.	System	11 Aug 2020 20:17:03
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered 'Day 99'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-11-15T02:03:01', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '36794f43-dcd2-49ea-8eb4-6bf4c5cab22c'	System	15 Nov 2020 07:03:31
User entered 'No (N)'	System	15 Nov 2020 07:03:31

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-11-15T02:03:11', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '36794f43-dcd2-49ea-8eb4-6bf4c5cab22c'	System	15 Nov 2020 07:03:31
User entered 'No (N)'	System	15 Nov 2020 07:03:31

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-11-15T02:03:29', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '36794f43-dcd2-49ea-8eb4-6bf4c5cab22c'	System	15 Nov 2020 07:03:31
User entered '15 Nov 2020 02:03:29'	System	15 Nov 2020 07:03:31

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 20:17:03

US3372089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:47
Data entry locked.	System	11 Aug 2020 20:17:03
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 20:17:03

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2020-11-22T08:14:02', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3cd5c7f7-e3e5-41a3-a989-fd06111f5a0e'	System	22 Nov 2020 13:14:17
User entered 'No (N)'	System	22 Nov 2020 13:14:17

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2020-11-22T08:14:06', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3cd5c7f7-e3e5-41a3-a989-fd06111f5a0e'	System	22 Nov 2020 13:14:17
User entered 'No (N)'	System	22 Nov 2020 13:14:17

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-11-22T08:14:13', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3cd5c7f7-e3e5-41a3-a989-fd06111f5a0e'	System	22 Nov 2020 13:14:17
User entered '22 Nov 2020 08:14:13'	System	22 Nov 2020 13:14:17

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2020-11-26T12:32:05', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '69e7212c-6fee-4197-b5af-6640fe5c97db'	System	26 Nov 2020 17:32:28
User entered 'No (N)'	System	26 Nov 2020 17:32:28

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2020-11-26T12:32:11', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '69e7212c-6fee-4197-b5af-6640fe5c97db'	System	26 Nov 2020 17:32:28
User entered 'No (N)'	System	26 Nov 2020 17:32:28

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-11-26T12:32:19', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '69e7212c-6fee-4197-b5af-6640fe5c97db'	System	26 Nov 2020 17:32:28
User entered '26 Nov 2020 12:32:19'	System	26 Nov 2020 17:32:28

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2020-12-03T06:49:36', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd156547b-17ca-4e6f-86bf-2b21a2134db0'	System	03 Dec 2020 11:49:57
User entered 'No (N)'	System	03 Dec 2020 11:49:57

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2020-12-03T06:49:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd156547b-17ca-4e6f-86bf-2b21a2134db0'	System	03 Dec 2020 11:49:57
User entered 'No (N)'	System	03 Dec 2020 11:49:57

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-12-03T06:49:48', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'd156547b-17ca-4e6f-86bf-2b21a2134db0'	System	03 Dec 2020 11:49:57
User entered '03 Dec 2020 06:49:48'	System	03 Dec 2020 11:49:57

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2020-12-10T16:05:24', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e99dcd0a-2fae-4bf8-abc-b-856e59c0d216'	System	10 Dec 2020 21:05:41
User entered 'No (N)'	System	10 Dec 2020 21:05:41

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2020-12-10T16:05:31', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e99dcd0a-2fae-4bf8-abcb-856e59c0d216'	System	10 Dec 2020 21:05:41
User entered 'No (N)'	System	10 Dec 2020 21:05:41

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-12-10T16:05:34', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'e99dcd0a-2fae-4bf8-abcb-856e59c0d216' User entered '10 Dec 2020 16:05:34'	System	10 Dec 2020 21:05:41
	System	10 Dec 2020 21:05:41

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2020-12-17T01:52:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '10d57bdd-bc11-4bc3-9784-dcb0adefeb0f'	System	17 Dec 2020 06:52:52
User entered 'No (N)'	System	17 Dec 2020 06:52:52

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2020-12-17T01:52:36', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '10d57bdd-bc11-4bc3-9784-dcb0adefeb0f'	System	17 Dec 2020 06:52:52
User entered 'No (N)'	System	17 Dec 2020 06:52:52

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-12-17T01:52:46', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '10d57bdd-bc11-4bc3-9784-dcb0adefeb0f' User entered '17 Dec 2020 01:52:46'	System	17 Dec 2020 06:52:52
	System	17 Dec 2020 06:52:52

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2020-12-26T13:03:29', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'aebf0289-33e9-4506-b598-21cc4daa16c6'	System	26 Dec 2020 18:03:58
User entered 'No (N)'	System	26 Dec 2020 18:03:58

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2020-12-26T13:03:35', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'aebf0289-33e9-4506-b598-21cc4daa16c6'	System	26 Dec 2020 18:03:58
User entered 'No (N)'	System	26 Dec 2020 18:03:58

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-12-26T13:03:46', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'aebf0289-33e9-4506-b598-21cc4daa16c6' User entered '26 Dec 2020 13:03:46'	System	26 Dec 2020 18:03:58
	System	26 Dec 2020 18:03:58

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2020-12-31T00:18:10', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '6cdef0d3-5b5a-40d0-a83b-14adc416163f'	System	31 Dec 2020 05:18:29
User entered 'No (N)'	System	31 Dec 2020 05:18:29

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2020-12-31T00:18:18', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '6cdef0d3-5b5a-40d0-a83b-14adc416163f'	System	31 Dec 2020 05:18:29
User entered 'No (N)'	System	31 Dec 2020 05:18:29

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2020-12-31T00:18:23', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '6cdef0d3-5b5a-40d0-a83b-14adc416163f' User entered '31 Dec 2020 00:18:23'	System	31 Dec 2020 05:18:29
	System	31 Dec 2020 05:18:29

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2021-01-07T08:28:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0b934a18-10e3-4add-a7fd-ded8f7c3dee5'	System	07 Jan 2021 13:29:02
User entered 'No (N)'	System	07 Jan 2021 13:29:02

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2021-01-07T08:28:48', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0b934a18-10e3-4add-a7fd-ded8f7c3dee5'	System	07 Jan 2021 13:29:02
User entered 'No (N)'	System	07 Jan 2021 13:29:02

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-01-07T08:28:55', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '0b934a18-10e3-4add-a7fd-ded8f7c3dee5'	System	07 Jan 2021 13:29:02
User entered '07 Jan 2021 08:28:55'	System	07 Jan 2021 13:29:02

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2021-01-14T05:37:35', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3b7e6564-4ac7-460c-b44d-0208283887d6'	System	14 Jan 2021 10:37:52
User entered 'No (N)'	System	14 Jan 2021 10:37:52

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2021-01-14T05:37:42', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3b7e6564-4ac7-460c-b44d-0208283887d6'	System	14 Jan 2021 10:37:52
User entered 'No (N)'	System	14 Jan 2021 10:37:52

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-01-14T05:37:46', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '3b7e6564-4ac7-460c-b44d-0208283887d6'	System	14 Jan 2021 10:37:52
User entered '14 Jan 2021 05:37:46'	System	14 Jan 2021 10:37:52

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2021-02-18T12:33:53', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered 'Yes (Y)'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2021-02-18T12:34:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered 'No (N)'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:21', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered 'Yes (Y)'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '1'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '1'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064' User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:30', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '0'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:38', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:45', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered 'Yes (Y)'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:34:49', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-18T12:35:07', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a7afd1f-a777-473a-bb2b-4bf70b04e064'	System	18 Feb 2021 17:35:24
User entered '18 Feb 2021 12:35:07'	System	18 Feb 2021 17:35:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2021-02-25T04:19:51-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered 'Yes (Y)'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2021-02-25T04:19:56-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered 'No (N)'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:06-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered 'Yes (Y)'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '1'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '1'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '0'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '0'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '0'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '1'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '1'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '1'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '0'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '0'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '0'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '0'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '0'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '0'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '1'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '0'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:38-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '0'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:20:58-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba'	System	25 Feb 2021 09:21:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:21:04-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered 'Yes (Y)'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:21:07-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba'	System	25 Feb 2021 09:21:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-02-25T04:21:12-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '268babf4-a7e4-4c1e-9b64-382230065bba' User entered '25 Feb 2021 04:21:12'	System	25 Feb 2021 09:21:24
	System	25 Feb 2021 09:21:24

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2021-03-04T00:04:52-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '43460757-0453-403e-b0bc-e7952a074534'	System	04 Mar 2021 05:07:35
User entered 'No (N)'	System	04 Mar 2021 05:07:35

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2021-03-04T00:04:57-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '43460757-0453-403e-b0bc-e7952a074534'	System	04 Mar 2021 05:07:35
User entered 'No (N)'	System	04 Mar 2021 05:07:35

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-03-04T00:05:07-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '43460757-0453-403e-b0bc-e7952a074534'	System	04 Mar 2021 05:07:35
User entered '04 Mar 2021 00:05:07'	System	04 Mar 2021 05:07:35

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2021-03-15T09:26:49-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'df7279a8-4f57-4418-bbf9-2f46d3c5b046'	System	15 Mar 2021 13:27:09
User entered 'No (N)'	System	15 Mar 2021 13:27:09

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2021-03-15T09:26:53-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'df7279a8-4f57-4418-bbf9-2f46d3c5b046'	System	15 Mar 2021 13:27:09
User entered 'No (N)'	System	15 Mar 2021 13:27:09

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-03-15T09:26:58-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'df7279a8-4f57-4418-bbf9-2f46d3c5b046'	System	15 Mar 2021 13:27:09
User entered '15 Mar 2021 09:26:58'	System	15 Mar 2021 13:27:09

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2021-03-18T08:51:53-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a981da7-133e-424f-ab2d-533156564221'	System	18 Mar 2021 12:52:10
User entered 'No (N)'	System	18 Mar 2021 12:52:10

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2021-03-18T08:51:57-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a981da7-133e-424f-ab2d-533156564221'	System	18 Mar 2021 12:52:10
User entered 'No (N)'	System	18 Mar 2021 12:52:10

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-03-18T08:52:03-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '9a981da7-133e-424f-ab2d-533156564221' User entered '18 Mar 2021 08:52:03'	System	18 Mar 2021 12:52:10
	System	18 Mar 2021 12:52:10

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2021-03-25T02:12:36-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '1fb118ef-d6a4-4130-ac84-38c8fc087570'	System	25 Mar 2021 06:12:53
User entered 'No (N)'	System	25 Mar 2021 06:12:53

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2021-03-25T02:12:41-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '1fb118ef-d6a4-4130-ac84-38c8fc087570'	System	25 Mar 2021 06:12:53
User entered 'No (N)'	System	25 Mar 2021 06:12:53

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-03-25T02:12:47-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '1fb118ef-d6a4-4130-ac84-38c8fc087570' User entered '25 Mar 2021 02:12:47'	System	25 Mar 2021 06:12:53
	System	25 Mar 2021 06:12:53

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2021-04-01T00:02:33-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'de650d49-3931-4249-a48f-2538a2816acc' User entered 'No (N)'	System	01 Apr 2021 04:04:23
	System	01 Apr 2021 04:04:23

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2021-04-01T00:02:38-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'de650d49-3931-4249-a48f-2538a2816acc'	System	01 Apr 2021 04:04:23
User entered 'No (N)'	System	01 Apr 2021 04:04:23

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-04-01T00:02:51-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'de650d49-3931-4249-a48f-2538a2816acc' User entered '01 Apr 2021 00:02:51'	System	01 Apr 2021 04:04:23
	System	01 Apr 2021 04:04:23

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2021-04-08T06:33:19-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7164e0fb-7469-4a41-9fb3-0fe158005bcd' User entered 'No (N)'	System	08 Apr 2021 10:33:40
	System	08 Apr 2021 10:33:40

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2021-04-08T06:33:28-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7164e0fb-7469-4a41-9fb3-0fe158005bcd' User entered 'No (N)'	System	08 Apr 2021 10:33:40
	System	08 Apr 2021 10:33:40

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-04-08T06:33:34-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '7164e0fb-7469-4a41-9fb3-0fe158005bcd' User entered '08 Apr 2021 06:33:34'	System	08 Apr 2021 10:33:40
	System	08 Apr 2021 10:33:40

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2021-04-15T01:03:58-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '37c19712-5064-4fc1-bf4a-4724a2ea20c7'	System	15 Apr 2021 05:04:15
User entered 'No (N)'	System	15 Apr 2021 05:04:15

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2021-04-15T01:04:03-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '37c19712-5064-4fc1-bf4a-4724a2ea20c7'	System	15 Apr 2021 05:04:15
User entered 'No (N)'	System	15 Apr 2021 05:04:15

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-04-15T01:04:08-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '37c19712-5064-4fc1-bf4a-4724a2ea20c7'	System	15 Apr 2021 05:04:15
User entered '15 Apr 2021 01:04:08'	System	15 Apr 2021 05:04:15

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2021-04-22T03:17:21-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'efde6bdc-d926-4998-a00a-83f6003f77be' User entered 'No (N)'	System	22 Apr 2021 07:17:48
	System	22 Apr 2021 07:17:48

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2021-04-22T03:17:27-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'efde6bdc-d926-4998-a00a-83f6003f77be' User entered 'No (N)'	System	22 Apr 2021 07:17:48
	System	22 Apr 2021 07:17:48

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-04-22T03:17:43-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'efde6bdc-d926-4998-a00a-83f6003f77be' User entered '22 Apr 2021 03:17:43'	System	22 Apr 2021 07:17:48
	System	22 Apr 2021 07:17:48

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[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 (2cd0020f83c721c3)', Time: '2021-04-29T02:54:28-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a29a7f5e-675d-4bd1-a2a8-bca3f421c542'	System	29 Apr 2021 06:54:58
User entered 'No (N)'	System	29 Apr 2021 06:54:58

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

Have you been exposed to someone with 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 (2cd0020f83c721c3)', Time: '2021-04-29T02:54:33-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a29a7f5e-675d-4bd1-a2a8-bca3f421c542'	System	29 Apr 2021 06:54:58
User entered 'No (N)'	System	29 Apr 2021 06:54:58

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-04-29T02:54:43-04:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: 'a29a7f5e-675d-4bd1-a2a8-bca3f421c542'	System	29 Apr 2021 06:54:58
User entered '29 Apr 2021 02:54:43'	System	29 Apr 2021 06:54:58

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 04:03:38

US3372089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:03:38
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 04:03:38

US3372089

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:12:37

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-03-04T00:05:23-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '066564cb-aecb-498b-8869-5a1ddb7f1a8d'	System	04 Mar 2021 05:08:16
User entered 'No (N)'	System	04 Mar 2021 05:08:16

US3372089

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:12:37

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cd0020f83c721c3)', Time: '2021-03-04T00:05:29-05:00', User OID: 'PatientReportedOutcome (US3372089)', ODM File OID: '066564cb-aecb-498b-8869-5a1ddb7f1a8d' User entered '04 Mar 2021 00:05:29'	System	04 Mar 2021 05:08:16
	System	04 Mar 2021 05:08:16

US3372089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 17:47:34
	(b) (4)	

US3372089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '4 Nov 2020'	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 17:47:34
	(b) (4)	

US3372089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 17:47:34

US3372089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 17:47:34
	(b) (4)	

US3372089

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 17:47:41
	(b) (4)	

US3372089

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:18
User entered 'I'	System	07 Jan 2021 17:47:41

US3372089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	07 Jan 2021 17:48:01

US3372089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '8 Dec 2020'	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 17:48:01
	(b) (4)	

US3372089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	07 Jan 2021 17:48:01

US3372089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 17:48:01
	(b) (4)	

US3372089

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 17:48:06
	(b) (4)	

US3372089

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User entered 'I'	System	07 Jan 2021 17:48:06

US3372089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	07 Jan 2021 17:48:16

US3372089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '7 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 17:48:16
	(b) (4)	

US3372089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 17:48:16
	(b) (4)	

US3372089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Danielle Theodore (b) (4)	07 Jan 2021 17:48:16
	(b) (4)	

US3372089

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	07 Jan 2021 17:48:22

US3372089

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User entered 'I'	System	07 Jan 2021 17:48:22

US3372089

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:39:28
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	05 Feb 2021 16:06:43

US3372089

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:39:28
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '5 Feb 2021'	(b) (4) Danielle Theodore (b) (4)	05 Feb 2021 16:06:43
	(b) (4)	

US3372089

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:39:28
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	05 Feb 2021 16:06:43

US3372089

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:39:28
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Danielle Theodore (b) (4)	05 Feb 2021 16:06:43
	(b) (4)	

US3372089

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:39:28
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	05 Feb 2021 16:06:53

US3372089

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:39:28
User entered 'I'	System	05 Feb 2021 16:06:53

US3372089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	09 Mar 2021 15:47:41

US3372089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
Signature has been broken.	(b) (4) Peter Jacob (b) (4)	02 Apr 2021 21:43:15
User entered '08 Mar 2021' reason for change: Data Entry Error	(b) (4) Peter Jacob (b) (4)	02 Apr 2021 21:43:15
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered '8 Mar 2021'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 15:47:41
	(b) (4)	

US3372089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered 'Clinic (Clinic)'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 15:47:41
	(b) (4)	

US3372089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User entered 'VISIT4'	System	09 Mar 2021 15:47:41

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User entered empty.	System	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User entered empty.	System	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User entered empty.	System	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User entered empty.	System	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User entered empty.	System	02 Apr 2021 21:43:20

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09

US3372089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09

US3372089

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered 'No (N)'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 16:35:18
	(b) (4)	

US3372089

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered empty.	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 16:35:18
	(b) (4)	

US3372089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 15:49:33
	(b) (4)	

US3372089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
Signature has been broken.	(b) (4) Peter Jacob (b) (4)	02 Apr 2021 21:43:27
User entered '08 Mar 2021' reason for change: Data Entry Error	(b) (4) Peter Jacob (b) (4)	02 Apr 2021 21:43:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered '8 Mar 2021'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 15:49:33
	(b) (4)	

US3372089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered '09:19'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 15:49:33
	(b) (4)	

US3372089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User entered '08 Mar 2021 09:19'	System	02 Apr 2021 21:43:27
User entered '8 Mar 2021 09:19'	System	09 Mar 2021 15:49:33

US3372089

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	09 Mar 2021 15:47:49

US3372089

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:35:09
User entered 'I'	System	09 Mar 2021 15:47:49

US3372089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:29
User signature succeeded.	Mira Baron (b) (4)	07 Apr 2021 18:52:49
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	07 Apr 2021 15:01:18

US3372089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:29
User signature succeeded.	Mira Baron (b) (4)	07 Apr 2021 18:52:49
User entered '7 Apr 2021'	(b) (4) Danielle Theodore (b) (4)	07 Apr 2021 15:01:18

US3372089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:29
User signature succeeded.	Mira Baron (b) (4)	07 Apr 2021 18:52:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	07 Apr 2021 15:01:18

US3372089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:29
User signature succeeded.	Mira Baron (b) (4)	07 Apr 2021 18:52:49
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	07 Apr 2021 15:01:18

US3372089

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:29
User signature succeeded.	Mira Baron (b) (4)	07 Apr 2021 18:52:49
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	07 Apr 2021 15:01:23

US3372089

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:29
User entered 'I'	System	07 Apr 2021 15:01:23

US3372089

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

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:17:25

US3372089

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

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '18 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 14:21:46
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:17:25

US3372089

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

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:17:25

US3372089

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

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 18:17:25

US3372089

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

Form: Unblinding

Generated On: 09 Jun 2021 17:12:37

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '18 Jan 2021' reason for change: Data Entry Error	(b) (4)	21 Jan 2021 14:21:54
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:17:55

US3372089

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

Form: Unblinding

Generated On: 09 Jun 2021 17:12:37

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
User entered '0'	(b) (4) Peter Jacob (b) (4)	02 Apr 2021 21:43:41
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 12:15:05

US3372089

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

Form: Unblinding

Generated On: 09 Jun 2021 17:12:37

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:17:55

US3372089

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

Form: Unblinding

Generated On: 09 Jun 2021 17:12:37

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:02
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Peter Jacob (b) (4)	02 Apr 2021 21:43:41
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 12:15:05

US3372089

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

Form: Unblinding

Generated On: 09 Jun 2021 17:12:37

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '18 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 14:21:54
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:17:55

US3372089

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

Form: Unblinding

Generated On: 09 Jun 2021 17:12:37

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:17:55

US3372089

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

Form: Unblinding

Generated On: 09 Jun 2021 17:12:37

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:17:55

US3372089

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

Form: Unblinding

Generated On: 09 Jun 2021 17:12:37

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:17:55

US3372089

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

Form: Unblinding

Generated On: 09 Jun 2021 17:12:37

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:17:55

US3372089

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

Form: Unblinding

Generated On: 09 Jun 2021 17:12:37

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered '1'	System	20 Jan 2021 18:17:55

US3372089

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

Form: Unblinding

Generated On: 09 Jun 2021 17:12:37

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'I'	System	20 Jan 2021 18:17:55

US3372089

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered empty.	System	20 Jan 2021 18:20:54
DataPoint set to visible.	System	20 Jan 2021 18:17:55

US3372089

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered empty.	System	20 Jan 2021 18:20:54
DataPoint set to visible.	System	20 Jan 2021 18:17:55

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	21 Jan 2021 14:22:05
User entered '18 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 14:22:05
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Jan 2021 14:21:46
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	21 Jan 2021 14:23:11
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	21 Jan 2021 14:22:05
User entered '10:40'	(b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered '18 Jan 2021 10:40'	System	21 Jan 2021 14:22:05
User entered '15 Jan 2021 10:40'	System	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '70'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'bpm'	System	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '17'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'breaths/min'	System	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '130'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'mmHg'	System	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '82'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'mmHg'	System	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered empty.	System	20 Jan 2021 18:20:54
DataPoint set to visible.	System	20 Jan 2021 18:17:55

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	21 Jan 2021 14:22:05
User entered '18 Jan 2021' reason for change: Data Entry Error	System	21 Jan 2021 14:22:05
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 14:21:46
User entered '15 Jan 2021'	System	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '11:38'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered '18 Jan 2021 11:38'	System	21 Jan 2021 14:22:05
User entered '15 Jan 2021 11:38'	System	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '70'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'bpm'	System	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'breaths/min'	System	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '124'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'mmHg'	System	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '77'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:20:54

US3372089

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'mmHg'	System	20 Jan 2021 18:20:54

US3372089

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:21:01

US3372089

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:21:01

US3372089

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

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:21:20

US3372089

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

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:21:20

US3372089

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

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:21:20

US3372089

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

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'mRNA-1273'	System	20 Jan 2021 18:21:20
DataPoint set to visible.	System	20 Jan 2021 18:17:55

US3372089

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

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	21 Jan 2021 14:23:11
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	21 Jan 2021 14:23:11
User entered '18 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 14:23:11
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	21 Jan 2021 14:21:46
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:21:20

US3372089

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

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '11:03'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:21:20

US3372089

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

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered '18 Jan 2021 11:03'	System	21 Jan 2021 14:23:11
User entered '15 Jan 2021 11:03'	System	20 Jan 2021 18:21:20

US3372089

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

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:21:20

US3372089

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

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'ONCE'	System	20 Jan 2021 18:21:20

US3372089

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

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 18:21:20

US3372089

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:18:06

US3372089

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	21 Jan 2021 14:23:17
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	21 Jan 2021 14:23:17
User entered '18 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 14:23:17
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Jan 2021 14:21:46
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:18:06

US3372089

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '10:12'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:18:06

US3372089

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered '18 Jan 2021 10:12'	System	21 Jan 2021 14:23:17
User entered '15 Jan 2021 10:12'	System	20 Jan 2021 18:18:06

US3372089

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:12:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:18:15

US3372089

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:12:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '18 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 14:23:23
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:18:15

US3372089

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:12:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '10:11'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:18:15

US3372089

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered '18 Jan 2021 10:11'	System	21 Jan 2021 14:23:23
User entered '15 Jan 2021 10:11'	System	20 Jan 2021 18:18:15

US3372089

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

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:18:19

US3372089

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

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'I'	System	20 Jan 2021 18:18:19

US3372089

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	25 Jan 2021 14:41:16

US3372089

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '25 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	25 Jan 2021 14:41:16
	(b) (4)	

US3372089

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	25 Jan 2021 14:41:16

US3372089

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Danielle Theodore (b) (4)	25 Jan 2021 14:41:16
	(b) (4)	

US3372089

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	25 Jan 2021 14:41:42

US3372089

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'I'	System	25 Jan 2021 14:41:42

US3372089

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered '1'	System	25 Jan 2021 14:41:42
DataPoint set to visible.	System	25 Jan 2021 14:41:42

US3372089

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:32:47

US3372089

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:32:47

US3372089

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:32:47

US3372089

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'OLD29'	System	16 Feb 2021 16:32:47

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '10:20'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered '15 Feb 2021 10:20'	System	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '67'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'bpm'	System	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '20'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'breaths/min'	System	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '130'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'mmHg'	System	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '84'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'mmHg'	System	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '11:20'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered '15 Feb 2021 11:20'	System	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '64'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'bpm'	System	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '20'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'breaths/min'	System	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '141'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'mmHg'	System	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '84'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'mmHg'	System	16 Feb 2021 16:34:23

US3372089

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:33

US3372089

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:33

US3372089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:46

US3372089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:46

US3372089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:46

US3372089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'mRNA-1273'	System	16 Feb 2021 16:34:46
DataPoint set to visible.	System	25 Jan 2021 14:41:42

US3372089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:46

US3372089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered '10:50'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:46

US3372089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered '15 Feb 2021 10:50'	System	16 Feb 2021 16:34:46

US3372089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:40:23
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:34:46

US3372089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'ONCE'	System	16 Feb 2021 16:34:46

US3372089

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'INTRAMUSCULAR'	System	16 Feb 2021 16:34:46

US3372089

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:30:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:35:02

US3372089

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'I'	System	16 Feb 2021 16:35:02

US3372089

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:49:42
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	22 Feb 2021 19:00:12
	(b) (4)	

US3372089

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:49:42
User entered '22 Feb 2021'	(b) (4) Danielle Theodore (b) (4)	22 Feb 2021 19:00:12
	(b) (4)	

US3372089

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:49:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	22 Feb 2021 19:00:12

US3372089

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:49:42
User entered empty.	(b) (4) Danielle Theodore (b) (4)	22 Feb 2021 19:00:12
	(b) (4)	

US3372089

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:49:42
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	22 Feb 2021 19:00:20
	(b) (4)	

US3372089

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'I'	System	22 Feb 2021 19:00:20

US3372089

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	16 Mar 2021 14:53:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Mar 2021 12:03:11
Query 'Data is required. Please complete.' answered with 'error' (Site from System).	Danielle Theodore (b) (4)	09 Mar 2021 16:34:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 15:47:10
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	09 Mar 2021 15:47:10
User entered empty; reason for change Data Entry Error	Danielle Theodore (b) (4)	09 Mar 2021 15:47:10
	(b) (4)	
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	09 Mar 2021 15:46:59
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	09 Mar 2021 15:45:09
	(b) (4)	

US3372089

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered '15 Mar 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:07
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	09 Mar 2021 15:46:59
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	09 Mar 2021 15:46:59
User entered empty; reason for change Data Entry Error	Danielle Theodore (b) (4) (b) (4)	09 Mar 2021 15:46:59
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	09 Mar 2021 15:45:09
User entered '8 Mar 2021'	Danielle Theodore (b) (4) (b) (4)	09 Mar 2021 15:45:09

US3372089

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:07
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	09 Mar 2021 15:47:10
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	09 Mar 2021 15:46:59
User entered empty; reason for change Data Entry Error	Danielle Theodore (b) (4) (b) (4)	09 Mar 2021 15:46:59
User entered 'Clinic (Clinic)'	Danielle Theodore (b) (4) (b) (4)	09 Mar 2021 15:45:09

US3372089

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'OLD57'	System	16 Mar 2021 14:53:07
User entered empty.	System	09 Mar 2021 15:47:10
User entered 'OLD57'	System	09 Mar 2021 15:45:09

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered '12:29'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered '15 Mar 2021 12:29'	System	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered '73'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'bpm'	System	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered '20'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'breaths/min'	System	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered '109'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'mmHg'	System	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered '72'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered 'mmHg'	System	16 Mar 2021 14:53:48

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02

US3372089

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:37

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02

US3372089

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:52

US3372089

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:52

US3372089

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:54:03

US3372089

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:54:03

US3372089

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
User entered '12:36'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:54:03

US3372089

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:02
User entered '15 Mar 2021 12:36'	System	16 Mar 2021 14:54:03

US3372089

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:12:37

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:09
User closed query 'Per CDM Re-query: Per diary dose 1 subject indicated Joint aches in several joints at DAY 1 -30 (11 Aug 2020 – 09 Sep 2020), Fatigue at DAY 3 -30 (13 Aug 2020 – 09 Sep 2020) and Muscle aches all over at Day 1-30 (11 Aug 2020 – 09 Sep 2020) which lasted beyond day 7 post injection. Please review and verify if these are Solicited Adverse Reaction that should be captured in the AE eCRF.	(b) (4), (b) (6)	01 May 2021 08:55:56
' (Site from DM). Query 'Per CDM Re-query: Per diary dose 1 subject indicated Joint aches in several joints at DAY 1 -30 (11 Aug 2020 – 09 Sep 2020), Fatigue at DAY 3 -30 (13 Aug 2020 – 09 Sep 2020) and Muscle aches all over at Day 1-30 (11 Aug 2020 – 09 Sep 2020) which lasted beyond day 7 post injection. Please review and verify if these are Solicited Adverse Reaction that should be captured in the AE eCRF.	Peter Jacob (b) (4) (b) (4)	30 Apr 2021 19:15:54
' answered with 'Subject experienced basal cell carcinoma around the same time as these AEs, the AEs went away shortly after the removal of the basal cell carcinoma which was located on right shoulder and left upper arm. Based on this information, these AEs are not considered SARs and are instead Adverse Events related to the basal cell carcinoma AEs' (Site from DM). User opened query 'Per CDM Re-query: Per diary dose 1 subject indicated Joint aches in several joints at DAY 1 -30 (11 Aug 2020 – 09 Sep 2020), Fatigue at DAY 3 -30 (13 Aug 2020 – 09 Sep 2020) and Muscle aches all over at Day 1-30 (11 Aug 2020 – 09 Sep 2020) which lasted beyond day 7 post injection. Please review and verify if these are Solicited Adverse Reaction that should be captured in the AE eCRF.	(b) (4), (b) (6)	30 Apr 2021 04:04:23
' (Site from DM).		

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:12:37

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per DM Re-query: Please confirm the following symptoms (fatigue, joint aches in several joints and muscle aches all over) reported beyond 7 days in eDIARY dose 1 should be reported in AE form. Review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 04:04:01
Query 'Per DM Re-query: Please confirm the following symptoms (fatigue, joint aches in several joints and muscle aches all over) reported beyond 7 days in eDIARY dose 1 should be reported in AE form. Review and update accordingly.' answered with 'symptoms did not last beyond 7 days post-dose' (Site from DM).	Peter Jacob (b) (4) (b) (4)	29 Apr 2021 20:59:11
User opened query 'Per DM Re-query: Please confirm the following symptoms (fatigue, joint aches in several joints and muscle aches all over) reported beyond 7 days in eDIARY dose 1 should be reported in AE form. Review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 09:33:05
Query 'Per DM Re-query: Please confirm the following symptoms reported beyond 7 days in eDIARY dose 1 should be reported in AE form. Review and update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 09:32:15
User opened query 'Per DM Re-query: Please confirm the following symptoms reported beyond 7 days in eDIARY dose 1 should be reported in AE form. Review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 09:32:04
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Dose 1 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)	26 Apr 2021 09:32:04

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:12:37

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Dose 1 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 source all AEs have been recorded.' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 20:12:51
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Dose 1 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)	19 Apr 2021 06:39:23
User closed query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 05:07:51
Query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' answered with 'All AEs within or near this time frame have been captured.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 16:26:28

US3372089

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:12:37

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 07:28:50
	(b) (4), (b) (6)	02 Mar 2021 17:57:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:02:30

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:22:20
Data point term sent to Coder	(b) (4)	
User entered 'Basal Cell Carcinoma - Right Shoulder Lateral.'	Coder Import (b) (4)	06 Oct 2020 16:22:20
	(b) (4)	
	System	06 Oct 2020 15:07:30
	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
User entered empty.	System	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
User entered empty.	System	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'l'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
User entered '0'	System	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37
User entered 'I'	System	06 Oct 2020 15:06:44

US3372089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:37

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms malignant site unspecified NEC, PT: Squamous cell carcinoma, LLT: Squamous cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 10:56:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 10:56:25
Data point term sent to Coder	System	06 Oct 2020 15:30:17
User entered 'Squamous Cell Carcinoma - Left Upper Arm Lateral.'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '18 Aug 2020'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
User entered empty.	System	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '8 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
User entered empty.	System	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:29:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'l'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	06 Oct 2020 15:29:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
User entered '0'	System	06 Oct 2020 15:29:34

US3372089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46
User entered '1'	System	06 Oct 2020 15:29:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:12:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered	(b) (4)	17 Feb 2021 18:38:56
'USA-US056-2021-mRNA-1273-P301000010'	System	17 Feb 2021 18:38:56
User entered 'New'	(b) (4), (b) (6)	17 Feb 2021 18:38:56

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle weakness conditions, PT: Muscular weakness, LLT: Muscle weakness lower limb - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:08:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:08:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle weakness conditions, PT: Muscular weakness, LLT: Lower extremities weakness of - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 00:42:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 00:42:04
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 20:01:50
Data point term sent to Coder	System	17 Feb 2021 18:07:19
User entered 'Muscle Weakness Lower Extremities'	Mary Sergalis (b) (4) (b) (4) (b) (4)	17 Feb 2021 18:06:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:32
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:35
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:37
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:39
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '16 Feb 2021'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'according to eMR start time is not clear. Please review and clarify. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 14:01:11
Query 'according to eMR start time is not clear. Please review and clarify. Thanks' answered with 'on 16FEB2021 the Subject reported SAEs at 08:00.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:46:25
User opened query 'according to eMR start time is not clear. Please review and clarify. Thanks' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:40:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '02:50'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Feb 2021 02:50'	System	17 Feb 2021 18:06:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:49:18
Signature has been broken.	(b) (4)	
	Mary Sergalis (b) (4)	24 Feb 2021 16:47:04
User entered 'No (N)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	24 Feb 2021 16:47:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:49:18
Signature has been broken.	(b) (4)	
	Mary Sergalis (b) (4)	24 Feb 2021 16:47:04
User entered '17 Feb 2021' reason for change: Data Entry Error	Mary Sergalis (b) (4)	24 Feb 2021 16:47:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:49:18
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Feb 2021 16:47:50
Signature has been broken.	Mary Sergalis (b) (4)	24 Feb 2021 16:47:50
User entered '11:57' reason for change: Data Entry Error	Mary Sergalis (b) (4)	24 Feb 2021 16:47:50
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 16:47:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4)	
	Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '17 Feb 2021 11:57'	System	24 Feb 2021 16:47:50
User entered empty.	System	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 00:43:59
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'No con meds, treatment given for this. Subject had been admitted for observation only' (Site from DM).	Mary Sergalis (b) (4)	16 Mar 2021 15:24:27
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 13:59:37
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '16 Feb 2021'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:49:18
Signature has been broken.	(b) (4)	24 Feb 2021 16:47:04
	Mary Sergalis (b) (4)	
User entered '17 Feb 2021' reason for change: Data Entry Error	Mary Sergalis (b) (4)	24 Feb 2021 16:47:04
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4)	
	Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	17 Feb 2021 18:08:08
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	17 Feb 2021 18:08:08
User entered 'No (N)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	17 Feb 2021 18:08:08
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	17 Feb 2021 18:06:41
User entered 'Unknown (UNK)'	Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:41
Signature has been broken.	(b) (4) Mary Sergalis (b) (4)	16 Mar 2021 15:34:35
User entered 'Related (RELATED)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	16 Mar 2021 15:34:35
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' canceled (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 00:04:35
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 00:01:03
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	17 Feb 2021 18:08:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 18:08:25
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	17 Feb 2021 18:08:25
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 18:06:41
User entered empty.	Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
Query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug as the subject has a history of neuropathy, arthritis, obesity and was using simvastatin' canceled (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 00:04:42
User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug as the subject has a history of neuropathy, arthritis, obesity and was using simvastatin' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 23:54:03
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Related (RELATED)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 14:21:18
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'updated' (Site from Safety).	Mary Sergalis (b) (4)	16 Mar 2021 15:34:50
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 23:52:21
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'I'	Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

US3372089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:49:18
Signature has been broken.	(b) (4)	
	Mary Sergalis (b) (4)	24 Feb 2021 16:47:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mary Sergalis (b) (4)	24 Feb 2021 16:47:04
Data Entry Error		
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User closed query 'PV Query: Did the subject undergo any testing while hospitalized (e.g., CSF, EMG, nerve conduction studies), or was it so short-lived that it was resolved before they did anything?' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 19:47:53
Query 'PV Query: Did the subject undergo any testing while hospitalized (e.g., CSF, EMG, nerve conduction studies), or was it so short-lived that it was resolved before they did anything?' answered with 'Hospitalization was to short-lived for tests to be conducted for the AEs.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 16:22:13
User opened query 'PV Query: Did the subject undergo any testing while hospitalized (e.g., CSF, EMG, nerve conduction studies), or was it so short-lived that it was resolved before they did anything?' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 13:46:04
User closed query 'PV Query: Could you please clarify when the subject became afebrile? (was it in the emergency room or a different timeframe).' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 14:29:05
User closed query 'PV Query: Please send a hospital discharge summary with exit diagnostic, examinations performed, and treatment with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. Please provide the investigator's rationale for assessing the event as related to the study drug as the subject has a history of neuropathy, arthritis, obesity and was using simvastatin.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 14:29:02
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 14:28:56
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)	17 Mar 2021 14:28:52

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 14:28:42
User closed query 'PV Query: Please provide any additional 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)	17 Mar 2021 14:21:42
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)	17 Mar 2021 14:21:36
Query 'PV Query: Please send a hospital discharge summary with exit diagnostic, examinations performed, and treatment with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. Please provide the investigator's rationale for assessing the event as related to the study drug as the subject has a history of neuropathy, arthritis, obesity and was using simvastatin.' answered with 'discharge summary was sent.' (Site from Safety).	Mary Sergalis (b) (4)	16 Mar 2021 15:35:09
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'none' (Site from Safety).	Mary Sergalis (b) (4)	16 Mar 2021 15:34:08

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'discharge summary was sent. Look for it' (Site from Safety).	Mary Sergalis (b) (4)	16 Mar 2021 15:33:47
Query 'PV Query: Could you please clarify when the subject became afebrile? (was it in the emergency room or a different timeframe).' answered with 'in the ER' (Site from Safety).	Mary Sergalis (b) (4)	16 Mar 2021 15:32:16
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 'already answered! Again not done' (Site from Safety).	Mary Sergalis (b) (4)	16 Mar 2021 15:32:04
Query 'PV Query: Please provide any additional 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 'as previous stated, subject was admitted for observation only' (Site from Safety).	Mary Sergalis (b) (4)	16 Mar 2021 15:31:25
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 'Note done' (Site from Safety).	Mary Sergalis (b) (4)	16 Mar 2021 15:30:56
User opened query 'PV Query: Could you please clarify when the subject became afebrile? (was it in the emergency room or a different timeframe).' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 01:17:21

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with exit diagnostic, examinations performed, and treatment with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. Please provide the investigator's rationale for assessing the event as related to the study drug as the subject has a history of neuropathy, arthritis, obesity and was using simvastatin.' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 00:03:36
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)	05 Mar 2021 23:53:00
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 00:02:38
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 00:01:40
User opened query 'PV Query: Please provide any additional 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)	02 Mar 2021 00:01:21
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)	02 Mar 2021 00:01:11

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'This was reported on 16-FEB-2021 via paper submission due to EDC being down.	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:06:41

Subject contacted the site regarding being in the ER due to having severe muscle weakness of the lower extremities and unable to stand, fever > 102, and urinary retention.

Subject received their second dose of mRNA 1273 on 15-FEB-2021.

Subjects first dose was on 18-JAN-2021.

PI, M. Baron MD spoke with the ER physician attending to the subject. Subject is presently afebrile, urinary retention resolved but still has weakness in both lower extremities and difficulty walking. Subject is being admitted for observation.

At present time no further information is available.'

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Folder: Adverse Events

Form: Adverse Events (3)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 18:06:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 18:06:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:12:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 18:06:41

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Folder: Adverse Events

Form: Adverse Events (4)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' '(Site from DM).	(b) (4), (b) (6)	18 Mar 2021 06:56:17
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'An Illness visit was not done, the symptom occurred within a day of the 2nd dose. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:24:01
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' '(Site from DM).	(b) (4), (b) (6)	15 Mar 2021 11:16:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User coded data point as SOC: General disorders and administration site conditions, HLG: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Pyrexia - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 18:24:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 18:24:08
Data point term sent to Coder	System	17 Feb 2021 18:10:26
User entered 'Pyrexia'	Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '16 Feb 2021'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 16:47:21
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Query 'Data is required. Please provide.' answered with 'time unknown' (Site from System).	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:10:15
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Feb 2021 18:09:51
User entered empty.	Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
User entered empty.	System	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Form: Adverse Events (4)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '16 Feb 2021'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Form: Adverse Events (4)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 16:47:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Query 'Data is required. Please provide.' answered with 'time unknown' (Site from System).	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:10:25
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Feb 2021 18:09:51
User entered empty.	Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
User entered empty.	System	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

US3372089

Folder: Adverse Events

Form: Adverse Events (4)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Related (RELATED)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

US3372089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

US3372089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

US3372089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'l'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

US3372089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

US3372089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

US3372089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:09:51

US3372089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4)	17 Feb 2021 18:09:51
	Mary Sergalis (b) (4)	

US3372089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
User entered '0'	System	17 Feb 2021 18:09:51

US3372089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55
User entered 'I'	System	17 Feb 2021 18:09:51

US3372089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:12:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:39:55

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User coded data point as SOC: Renal and urinary disorders, HLG: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	17 Feb 2021 18:24:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:24:28
Data point term sent to Coder	System	17 Feb 2021 18:12:34
User entered 'Urinary Retention'	Mary Sergalis (b) (4) (b) (4) (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '16 Feb 2021'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 16:48:03
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	(b) (4)	
	Mary Sergalis (b) (4)	17 Feb 2021 18:11:47
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Feb 2021 18:11:37
User entered empty.	Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
User entered empty.	System	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '16 Feb 2021'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 16:48:05
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	(b) (4)	
	Mary Sergalis (b) (4)	17 Feb 2021 18:11:53
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Feb 2021 18:11:37
User entered empty.	Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
User entered empty.	System	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4)	17 Feb 2021 18:11:37
	Mary Sergalis (b) (4)	

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4)	17 Feb 2021 18:11:37
	Mary Sergalis (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Related (RELATED)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'l'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '0'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4) Mary Sergalis (b) (4)	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:53
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered empty.	(b) (4)	17 Feb 2021 18:11:37
	Mary Sergalis (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
User entered '0'	System	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01
User entered '1'	System	17 Feb 2021 18:11:37

US3372089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:12:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:12:37

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:54:51

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Sep 2020 15:57:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:57:48
Data point term sent to Coder	System	29 Sep 2020 15:56:41
User entered 'simvastatin'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'hyperlipidemia'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '20'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:56:21
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 2017'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 15:56:21
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 15:56:21

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Sep 2020 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) (b) (4)	29 Sep 2020 15:58:39
Data point term sent to Coder	System	29 Sep 2020 15:57:42
User entered 'gabapentin'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:50

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	29 Sep 2020 15:56:50
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'peripheral neuropathy'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:50

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '300'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:56:50

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:50

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 15:56:50
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:56:50
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:50

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:50

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 15:56:50
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:56:50
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:50

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:56:50

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 15:56:50
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:56:50
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:56:50

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:56:50

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 15:56:50

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Sep 2020 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) (b) (4)	29 Sep 2020 15:58:39
Data point term sent to Coder	System	29 Sep 2020 15:57:43
User entered 'tylenol'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:57:22

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:57:22
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'generalized arthritis'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:57:22

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '500'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:57:22

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:57:22

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 15:57:22
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered 'twice daily (BID)'	Peter Jacob (b) (4)	29 Sep 2020 15:57:22
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 15:57:22
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:57:22

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 15:57:22
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered 'un UNK 2018'	Peter Jacob (b) (4)	29 Sep 2020 15:57:22
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:57:22

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:57:22

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 15:57:22
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:57:22

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Sep 2020 15:57:22

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:57:22

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 15:57:22

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Sep 2020 15:59:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:59:43
Data point term sent to Coder	System	29 Sep 2020 15:58:45
User entered 'omeprazole'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:58:28

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	29 Sep 2020 15:58:28
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'gastroesophageal reflux disease'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:58:28

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '20'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:58:28

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:58:28

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 15:58:28
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:58:28

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:58:28

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:58:28

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 15:58:28
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered 'un Aug 2018'	Peter Jacob (b) (4)	29 Sep 2020 15:58:28
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:58:28

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:58:28

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 15:58:28
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:58:28

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:58:28

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:58:28

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 15:58:28

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Sep 2020 16:00:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:00:44
Data point term sent to Coder	System	29 Sep 2020 15:59:46
User entered 'pneumonia vaccine'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'pneumonia prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0.5'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User entered empty.	System	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User entered empty.	System	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:28:02
User entered empty.	System	29 Sep 2020 15:59:01

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
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)	29 Sep 2020 16:01:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 16:01:49
Data point term sent to Coder	System	29 Sep 2020 16:00:49
User entered 'influenza vaccine'	Peter Jacob (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'influenza prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un Sep 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'un Sep 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User entered empty.	System	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User entered empty.	System	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User entered empty.	System	29 Sep 2020 16:00:25

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Sep 2020 16:18:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:18:46
Data point term sent to Coder	System	29 Sep 2020 16:01:51
User entered 'hydrocortisone cream 2.5%'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:01:03

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	29 Sep 2020 16:01:03
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'bilateral upper extremity dermatosis'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:01:03

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '1'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:01:03

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered 'Other (OTHER)'	Peter Jacob (b) (4)	29 Sep 2020 16:01:03
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered 'dab'	Peter Jacob (b) (4)	29 Sep 2020 16:01:03
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered 'once daily (QD)'	Peter Jacob (b) (4)	29 Sep 2020 16:01:03
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 16:01:03
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered 'Topical (TOPICAL)'	Peter Jacob (b) (4)	29 Sep 2020 16:01:03
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 16:01:03
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered 'un UNK 2005'	Peter Jacob (b) (4)	29 Sep 2020 16:01:03
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:01:03

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:01:03

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	29 Sep 2020 16:01:03
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	29 Sep 2020 16:01:03
	(b) (4)	

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:01:03

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:01:03

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 16:01:03

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
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)	05 Nov 2020 15:55:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 15:55:21
Data point term sent to Coder	System	05 Nov 2020 15:54:48
User entered 'Influenza Vaccine'	Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
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) (4), (b) (6)	19 Jan 2021 12:36:48
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	18 Jan 2021 16:38:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	18 Jan 2021 16:38:29
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)	15 Jan 2021 21:50:53
User entered 'No (N)'	Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Influenza Prophylaxis/Prevention'	(b) (4) Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0.5'	(b) (4) Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'mL (mL)'	(b) (4) Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'once (ONCE)'	(b) (4) Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '25 Sep 2020'	(b) (4) Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '0'	(b) (4) Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '25 Sep 2020'	(b) (4) Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User entered empty.	System	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User entered empty.	System	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:31:42
User entered empty.	System	05 Nov 2020 15:53:49

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
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)	17 Feb 2021 18:24:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:24:29
Data point term sent to Coder	System	17 Feb 2021 18:13:36
User entered 'Acetaminophen'	Mary Sergalis (b) (4) (b) (4) (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered 'Pyrexia'	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered '500'	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered 'mg (mg)'	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered 'as needed (PRN)'	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered 'Oral (ORAL)'	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered '16 Feb 2021'	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:12:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 18:12:57

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:12:37

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	06 Oct 2020 15:42:26
User entered 'No (N)'	Peter Jacob (b) (4)	29 Sep 2020 15:54:45

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:12:37

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:45:31

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:12:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Biopsy Basal Cell Carcinoma - Right Shoulder Lateral'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:45:31

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:12:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:45:31

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:12:37

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:45:31

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:12:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:47:18

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:12:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Biopsy Squamous Cell Carcinoma - Left Posterior Upper Arm'	(b) (4), (b) (6)	06 Oct 2020 15:47:18

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:12:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:47:18

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:12:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:47:18

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:12:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:48:22

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:12:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Basal Cell Carcinoma Excision - Right Shoulder Lateral.'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:48:22

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:12:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:48:22

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:12:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:42
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:48:22

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:12:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:49:27

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:12:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Excision Squamous Cell Carcinoma - Left Posterior Upper Arm.'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:49:27

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:12:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:49:27

US3372089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:12:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:25:00
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:49:27

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'USA-US056-2021-MRNA-1273-P301000010'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Yes (Y)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Yes (Y)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Mira'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Baron'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered '2277 Palm beach Lakes Blvd'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'West Palm Beach'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	26 Feb 2021 01:58:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:32:02
Signature has been broken.	System	25 Feb 2021 18:31:50
User entered empty.	System	25 Feb 2021 18:31:50
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:49:18
User entered 'florida'	(b) (4) Mary Sergalis (b) (4)	24 Feb 2021 16:48:32

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered '33409'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:32:02
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'US'	(b) (4) System	17 Feb 2021 18:40:17

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Mar 2021 14:31:34
User signature succeeded.	Mira Baron (b) (4)	26 Feb 2021 01:58:58
	(b) (4)	
Signature has been broken.	System	25 Feb 2021 18:31:50
User entered '2'	System	25 Feb 2021 18:31:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 18:40:17

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'USA-US056-2021-MRNA-1273-P301000010'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Yes (Y)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Yes (Y)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Mira'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Baron'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered '2277 Palm beach Lakes Blvd'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'West Palm Beach'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	26 Feb 2021 01:58:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:32:02
Signature has been broken.	System	25 Feb 2021 18:31:50
User entered empty.	System	25 Feb 2021 18:31:50
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:49:18
User entered 'florida'	(b) (4) Mary Sergalis (b) (4)	24 Feb 2021 16:48:32

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered '33409'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:32:02
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'US'	(b) (4) System	17 Feb 2021 18:40:17

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Mar 2021 14:31:34
User signature succeeded.	Mira Baron (b) (4)	26 Feb 2021 01:58:58
	(b) (4)	
Signature has been broken.	System	25 Feb 2021 18:31:50
User entered '2'	System	25 Feb 2021 18:31:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 18:40:17

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:12:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered '17/Feb/2021 13:40'	(b) (4) System	17 Feb 2021 18:40:17

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:12:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:32:02
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 18:40:17

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'USA-US056-2021-MRNA-1273-P301000010'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Yes (Y)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Yes (Y)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Mira'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Baron'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered '2277 Palm beach Lakes Blvd'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'West Palm Beach'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	26 Feb 2021 01:58:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:32:02
Signature has been broken.	System	25 Feb 2021 18:31:50
User entered empty.	System	25 Feb 2021 18:31:50
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:49:18
User entered 'florida'	(b) (4) Mary Sergalis (b) (4)	24 Feb 2021 16:48:32

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered '33409'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:32:02
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'US'	(b) (4) System	17 Feb 2021 18:40:17

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Mar 2021 14:31:34
User signature succeeded.	Mira Baron (b) (4)	26 Feb 2021 01:58:58
	(b) (4)	
Signature has been broken.	System	25 Feb 2021 18:31:50
User entered '2'	System	25 Feb 2021 18:31:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 18:40:17

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:12:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	26 Feb 2021 01:58:58
User entered '25/Feb/2021 13:31'	(b) (4) System	25 Feb 2021 18:31:50

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:12:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	26 Feb 2021 01:58:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:32:02
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 18:31:50

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'USA-US056-2021-MRNA-1273-P301000010'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Yes (Y)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Yes (Y)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'No (N)'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Mira'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'Baron'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered '2277 Palm beach Lakes Blvd'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered 'West Palm Beach'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	26 Feb 2021 01:58:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:32:02
Signature has been broken.	System	25 Feb 2021 18:31:50
User entered empty.	System	25 Feb 2021 18:31:50
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:49:18
User entered 'florida'	(b) (4) Mary Sergalis (b) (4)	24 Feb 2021 16:48:32

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:39:38
User entered '33409'	System	17 Feb 2021 18:38:56

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:57:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:32:02
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
User entered 'US'	(b) (4) System	17 Feb 2021 18:40:17

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Mar 2021 14:31:34
User signature succeeded.	Mira Baron (b) (4)	26 Feb 2021 01:58:58
	(b) (4)	
Signature has been broken.	System	25 Feb 2021 18:31:50
User entered '2'	System	25 Feb 2021 18:31:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 20:01:50
	(b) (4)	
User entered '1'	System	17 Feb 2021 18:40:17

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:12:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:40:51
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:49:08
User entered '17/Mar/2021 10:31'	(b) (4) System	17 Mar 2021 14:31:34

US3372089

Folder: SAE USA-US056-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:12:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:40:51
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:49:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:31:54
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 14:31:34