

US3352299 (Prod: Research Centers of America - ERG)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:01:01

All time stamps listed in this document are displayed in GMT

US3352299

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:01

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

Date of Birth (MMM yyyy)	(b) (6) 1972
Age	48
Age Units	YEARS
Age (Derived)	48
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

Generated On: 26 Nov 2020 11:01:01

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:01:01

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:01

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:01

Condition	NEARSIGHTED
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:01

Condition	MYOPIA
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:01

Condition	FARSIGHTED
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:01

Condition	HYPEROPIA
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:01

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:01

Condition	HYPOTHYROIDISM
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 (7)

Generated On: 26 Nov 2020 11:01:01

Condition	KIDNEY STONES
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 (8)

Generated On: 26 Nov 2020 11:01:01

Condition	KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:01

Condition	LEFT KNEE MENISCUS LESION
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:01

Condition	LEFT SHOULDER INTERNAL FIXATION DUET DISLOCATION
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:01

Condition	RIGHT TIBIA FRACTURE
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:01

Condition	BRADYCARDIA
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: Medical History (13)

Generated On: 26 Nov 2020 11:01:01

Condition	PULMONARY EMBOLISM
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:01

Condition	SURGERY - BILATERAL LASIK
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:01

Condition	SURGERY - RIGHT TIBIA FRACTURE REPAIR
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:01

Condition	SURGERY - LEFT SHOULDER DISLOCATED (FIXATION)
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:01

Condition	SURGERY - LEFT KNEE ARTHROSCOPY
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:01

Condition	SURGERY - VASECTOMY
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	1 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:25 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 10:25
Height (<i>xxx.x</i>)	187.0 cm
Weight (<i>xxx.x</i>)	110.0 kg
BMI (<i>xxx.x</i>)	31.45643 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

Generated On: 26 Nov 2020 11:01:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

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

GOES TO SHOP AND RESTAURANT

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

v6.020 DTW (1102)

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:01

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 110587

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:01

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 10:25
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	45 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	12:14 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 12:14
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	44 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 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

Generated On: 26 Nov 2020 11:01:01

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	1 SEP 2020
What was the treatment time? (00:00-23:59)	11:44 (24 HR)
Treatment Date and Time (derived)	1 SEP 2020 11:44
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
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

Generated On: 26 Nov 2020 11:01:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	1 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:27 (24 HR)
Collection date and time (derived)	1 SEP 2020 11:27

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:01

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

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

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: 26 Nov 2020 11:01:01

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °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

01 SEP 2020 12:24

PC Open Date & Time

01 SEP 2020 12:04

PC Close Date & Time

01 SEP 2020 14:34

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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	01 SEP 2020 21:11
PC Open Date & Time	01 SEP 2020 15:29
PC Close Date & Time	02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 22:33

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 19:26

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 08:18

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

05 SEP 2020 22:25

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

06 SEP 2020 22:22

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 22:36

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 12:24

PC Open Date & Time

01 SEP 2020 12:04

PC Close Date & Time

01 SEP 2020 14:34

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 21:14

PC Open Date & Time

01 SEP 2020 15:29

PC Close Date & Time

02 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

02 SEP 2020 22:33

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

03 SEP 2020 19:26

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 08:17

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

05 SEP 2020 22:24

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

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

06 SEP 2020 22:23

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

07 SEP 2020 22:36

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 12:25
PC Open Date & Time	01 SEP 2020 12:04
PC Close Date & Time	01 SEP 2020 14:34

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 21:14
PC Open Date & Time	01 SEP 2020 15:29
PC Close Date & Time	02 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 22:33
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 19:27
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 08:17
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 22:24
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 22:24
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 22:35
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3352299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

Was Contact Attempted?

Yes ☒

No ☐

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

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

Was Contact Attempted?

Yes ☒

No ☐

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

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 09:10
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:25
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3352299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:01

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	29 SEP 2020
What was the treatment time? (00:00-23:59)	09:55 (24 HR)
Treatment Date and Time (derived)	29 SEP 2020 09:55
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3352299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	29 SEP 2020
Collection time (<i>00:00-23:59</i>)	09:29 (24 HR)
Collection date and time (derived)	29 SEP 2020 09:29

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:01

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:24	29 SEP 2020 09:24
Nasopharyngeal Swab 2	No		

US3352299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

29 SEP 2020 10:28

PC Open Date & Time

29 SEP 2020 10:15

PC Close Date & Time

29 SEP 2020 12:45

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.2 °F

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

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

PC Time Stamp	29 SEP 2020 19:37
PC Open Date & Time	29 SEP 2020 13:40
PC Close Date & Time	30 SEP 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

101.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 18:53

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

01 OCT 2020 20:27

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **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

03 OCT 2020 06:52

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 12:12

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 07:01

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **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

05 OCT 2020 17:35

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 10:28

PC Open Date & Time

29 SEP 2020 10:15

PC Close Date & Time

29 SEP 2020 12:45

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 19:37

PC Open Date & Time

29 SEP 2020 13:40

PC Close Date & Time

30 SEP 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

30 SEP 2020 18:53

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

01 OCT 2020 20:28

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

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

03 OCT 2020 06:52

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

03 OCT 2020 12:13

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

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

05 OCT 2020 07:02

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

05 OCT 2020 17:36

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 10:29
PC Open Date & Time	29 SEP 2020 10:15
PC Close Date & Time	29 SEP 2020 12:45

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 19:38
PC Open Date & Time	29 SEP 2020 13:40
PC Close Date & Time	30 SEP 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 18:55
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 20:28
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 06:53
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 12:13
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 07:02
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 17:36
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3352299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

Was Contact Attempted?

Yes ☒

No ☐

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

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

Was Contact Attempted?

Yes ☒

No ☐

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

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

Was Contact Attempted?

Yes ☒

No ☐

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

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352299

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:16 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 09:16
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	98 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:01

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3352299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	27 OCT 2020
Collection time (<i>00:00-23:59</i>)	09:30 (24 HR)
Collection date and time (derived)	27 OCT 2020 09:30

US3352299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 NOV 2020 07:34:37
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	11 NOV 2020 08:34:35
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 08:32:30

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 61
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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

29 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 68
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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

05 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 75
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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

Patient Cloud Open Date & Time	03 DEC 2020 00:01
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Patient Cloud Close Date & Time	07 DEC 2020 23:59
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US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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 <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 250

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 257

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 292

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 313

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

Patient Cloud Open Date & Time	12 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 376

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

Patient Cloud Open Date & Time	21 OCT 2021 00:01
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Patient Cloud Close Date & Time	25 OCT 2021 23:59
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US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
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Patient Cloud Open Date & Time	02 DEC 2021 00:01
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Patient Cloud Close Date & Time	06 DEC 2021 23:59
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US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 488

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 502

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 509

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 523

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 537

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 544

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 551

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 558

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 565

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 572

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 579

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

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

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

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

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

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

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 ☐

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 586

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 663

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 677

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 754

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

DAY 782

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

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

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

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

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

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

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

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Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

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Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

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Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:01:01

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"/>

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:01:01

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 11:01:01

Visit Date

Please check all assessments that apply for this visit

Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

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Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:01

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

AEID	USA-US066-2020-MRNA-1273-P30 1000005
Adverse event	DISSEMINATED VESICULAR RASH ALL OVER BODY
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)	08 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" 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)	08 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

SUBJECT STARTED WITH
BLISTERS ALL OVER HIS BODY
MORE PROMINENT TO HIS
MOUTH. HE WENT TO FAMILY
DOCTOR YESTERDAY AND
WAS RECOMMENDED TO GO
TO THE HOSPITAL IN VIEW OF
HIS CLINICAL PRESENTATION.
SUBJECT'S WIFE REPORTED HE
WAS ADMITTED IN THE
HOSPITAL YESTERDAY
11NOV2020 AT 1030 AM. HAD A
SKIN BIOPSY DONE IN WHICH
RESULTS ARE PENDING. SHE
MENTIONED HE WAS GIVEN A
STERIOD ANTIVIRAL AND PAIN
MEDICATIONS. PENDING
MEDICAL RECORDS.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

AEID	
Adverse event	ELEVATED TRANSAMINASE LEVEL
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" 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)	11 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

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

Generated On: 26 Nov 2020 11:01:01

AEID	
Adverse event	RASH SKIN ERUPTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
DATA OBTAINED FROM SUBJECTS MEDICAL RECORDS WHICH HAVE BEEN REDACTED AND SUBMITTED TO SAFETY.	
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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:01:01

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)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	SYNTHROID
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPOTHYROIDISM
Dose per administration	200
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	BETHAMETHASONE 0.05%
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	DISSEMINATED VESICULAR RASH
Dose per administration	1
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	APPLICATION
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input checked="" type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

	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)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (3)

Generated On: 26 Nov 2020 11:01:01

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

	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)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 15 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	VALTREX
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DISSEMINATED VESICULAR RASH
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input checked="" type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

	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"/>
<hr/>		
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		15 NOV 2020
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	CLARITIN (LORATADINE)
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	RASK SKIN ERUPTION ALL OVER BODY
Dose per administration	10
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

	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)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
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"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	DILAUDID
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	RASH SKIN ERUPTION ALL OVER BODY
Dose per administration	0.5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

	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 checked="" type="radio"/>
If route of administration is Other, specify	INTRAVENOUS PUSH	
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	ALUMINUM HYDROXIDE/ DIPHENHYDRAMINE/ LIDOCAINE/ MAGNESIUM HYDROXIDE/ SIMETHICORE TOPICAL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	RASH SKIN ALL OVER BODY
Dose per administration	40
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input checked="" type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input checked="" type="checkbox"/> Subcutaneous <input type="checkbox"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 NOV 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"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	PEPCID
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	GASTRIC PROPHYLAXIS
Dose per administration	20 / 2
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MG / ML
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	21 NOV 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	HYCHROMORPHONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	RASH SKIN ERUPTION
Dose per administration	0.5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 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"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	ONDANSETRON
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	RASH SKIN ERUPTION
Dose per administration	4
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	PREDNISONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	RASH SKIN ERUPTION
Dose per administration	30
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

	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 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	PREDNISONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	RASH SKIN ERUPTION
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

	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)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

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

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

	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)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	SODIUM CHLORIDE 0.9%
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	RASH SKIN ERUPTION
Dose per administration	1000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 NOV 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	TRIAMCINOLONE 0.01%
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	RASH SKIN ERUPTION
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	APPLICATION
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input checked="" type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

	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)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	RASH SKIN ERUPTION
Dose per administration	1000
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

	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)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 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"/>

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:01:01

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:01:01

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
11 NOV 2020	PUNCH BIOPSY	Adverse Event	
13 NOV 2020	SKIN BIOPSY RIGHT ARM	Adverse Event	
12 NOV 2020	SKIN BIOPSY	Adverse Event	

US3352299

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:01:01

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3352299

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:01

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

SAEID	USA-US066-2020-MRNA-1273-P301000005
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	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:01:01

SAEID	USA-US066-2020-MRNA-1273-P301000005
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	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	13/NOV/2020 08:23
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

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:01:01

SAEID	USA-US066-2020-MRNA-1273-P301000005
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	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	18/NOV/2020 14:33
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

US3352299 (Prod: Research Centers of America - ERG)

US3352299

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:01

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3352299'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	01 Sep 2020 14:14:48

US3352299

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:46:06

US3352299

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 14:14:50

US3352299

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 17:46:06

US3352299

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	01 Sep 2020 17:46:06

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1972'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 14:14:51

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

[Age](#)

Audit	User	Time (GMT)
User entered '48'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '48'	System	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

White

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:01

Not reported

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:46:28

US3352299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2020'	System	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:01

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:01

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 16:22:56

US3352299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 14:14:50

US3352299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 16:23:02

US3352299

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 16:23:02

US3352299

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:46:49

US3352299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:48:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:48:51
Data point term sent to Coder	System	01 Sep 2020 17:48:01
User entered 'NEARSIGHTED'	(b) (4), (b) (6)	01 Sep 2020 17:47:05

US3352299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1986'	(b) (4), (b) (6)	01 Sep 2020 17:47:05

US3352299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:47:05

US3352299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:09:12
User opened query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:06:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:47:05

US3352299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:47:05

US3352299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:47:05

US3352299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1986'	System	01 Sep 2020 17:47:05

US3352299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1986'	System	01 Sep 2020 17:47:05

US3352299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:47:05

US3352299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:47:05

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Coders Import Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	(b) (4)	01 Sep 2020 17:48:50
User coded data point as Term Coded data point by User: Coders System - version MedDRA\\23.0.	(b) (4)	01 Sep 2020 17:48:50
Data point term sent to Coders System	System	01 Sep 2020 17:48:01
User entered 'MYOPIA'	(b) (4), (b) (6)	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1986'	(b) (4), (b) (6)	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:10:02
User opened query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:06:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1986'	System	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:01

Start Year (derived)

Audit	User	Time (GMT)
User entered '1986'	System	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:47:15

US3352299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Farsighted - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:48:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	01 Sep 2020 17:48:51
Data point term sent to Coder	System	01 Sep 2020 17:48:02
User entered 'FARSIGHTED'	(b) (4), (b) (6)	01 Sep 2020 17:47:26

US3352299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1986'	(b) (4), (b) (6)	01 Sep 2020 17:47:26

US3352299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:47:26

US3352299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:10:29
User opened query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:07:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:47:26

US3352299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:47:26

US3352299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:47:26

US3352299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1986'	System	01 Sep 2020 17:47:26

US3352299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1986'	System	01 Sep 2020 17:47:26

US3352299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:47:26

US3352299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:47:26

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:48:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	01 Sep 2020 17:48:51
Data point term sent to Coder	System	01 Sep 2020 17:48:02
User entered 'HYPEROPIA'	(b) (4), (b) (6)	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1986'	(b) (4), (b) (6)	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:11:03
User opened query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:07:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1986'	System	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:01

Start Year (derived)

Audit	User	Time (GMT)
User entered '1986'	System	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:47:39

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:49:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:49:54
Data point term sent to Coder	System	01 Sep 2020 17:49:03
User entered 'ASTIGMATISM'	(b) (4), (b) (6)	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:11:37
User opened query 'Per DM CLR: Ongoing is marked for this condition. Please review and confirm since a procedure for this condition (MH# 14) was reported (UN UNK 1998-UN UNK 1998). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:07:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:48:18

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:49:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:49:54
Data point term sent to Coder	System	01 Sep 2020 17:49:03
User entered 'HYPOTHYROIDISM'	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	(b) (4), (b) (6)	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2005'	System	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:48:33

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:49:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:49:53
Data point term sent to Coder	System	01 Sep 2020 17:49:04
User entered 'KIDNEY STONES'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	(b) (4), (b) (6)	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	(b) (4), (b) (6)	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:01

Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2012'	System	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2012'	System	01 Sep 2020 17:48:51

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:50:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:50:45
Data point term sent to Coder	System	01 Sep 2020 17:50:07
User entered 'KIDNEY STONES'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	(b) (4), (b) (6)	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	(b) (4), (b) (6)	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:01

Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2019'	System	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2019'	System	01 Sep 2020 17:49:08

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus lesion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 21:34:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 21:34:38
Data point term sent to Coder	System	01 Sep 2020 17:51:07
User entered 'LEFT KNEE MENISCUS LESION'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	(b) (4), (b) (6)	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	(b) (4), (b) (6)	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2008'	System	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2008'	System	01 Sep 2020 17:50:23

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder operation, LLT: Shoulder operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 07:24:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 07:24:41
Data point term sent to Coder	System	01 Sep 2020 17:53:11
User entered 'LEFT SHOULDER INTERNAL FIXATION DUET DISLOCATION'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1998'	System	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1998'	System	01 Sep 2020 17:52:18

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Tibia fracture, LLT: Tibia fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:54:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:54:46
Data point term sent to Coder	System	01 Sep 2020 17:54:12
User entered 'RIGHT TIBIA FRACTURE'	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1998'	System	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1998'	System	01 Sep 2020 17:53:34

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:54:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	01 Sep 2020 17:54:46
Data point term sent to Coder	System	01 Sep 2020 17:54:12
User entered 'BRADYCARDIA'	(b) (4), (b) (6)	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	(b) (4), (b) (6)	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2000'	System	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:53:45

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:58:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:58:49
Data point term sent to Coder	System	01 Sep 2020 17:58:21
User entered 'PULMONARY EMBOLISM'	(b) (4), (b) (6)	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	(b) (4), (b) (6)	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	(b) (4), (b) (6)	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:01

Start Year (derived)

Audit	User	Time (GMT)
User entered '2018'	System	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2018'	System	01 Sep 2020 17:57:41

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:01

[Condition](#)

Audit	User	Time (GMT)
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) (6)	29 Oct 2020 16:05:41
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)	16 Oct 2020 16:08:17
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:11:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:11:47
Data point term sent to Coder	System	01 Sep 2020 17:58:21
User entered 'SURGERY - BILATERAL LASIK'	(b) (4), (b) (6)	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1998'	System	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1998'	System	01 Sep 2020 17:58:15

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 12:15:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 12:15:15
Data point term sent to Coder	System	01 Sep 2020 17:59:22
User entered 'SURGERY - RIGHT TIBIA FRACTURE REPAIR'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1998'	System	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1998'	System	01 Sep 2020 17:58:49

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:01

[Condition](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition LEFT SHOULDER INTERNAL FIXATION DUET DISLOCATION (MH# 10). If yes, please ensure only one entry is recorded. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:23:08
User opened query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition LEFT SHOULDER INTERNAL FIXATION DUET DISLOCATION (MH# 10). If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:08:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder operation, LLT: Shoulder operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 09:00:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 09:00:23
Data point term sent to Coder	System	01 Sep 2020 18:00:25
User entered 'SURGERY - LEFT SHOULDER DISLOCATED (FIXATION)'	(b) (4), (b) (6)	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1998'	System	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1998'	System	01 Sep 2020 17:59:55

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy L knee - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 09:13:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 09:13:09
Data point term sent to Coder	System	01 Sep 2020 18:00:26
User entered 'SURGERY - LEFT KNEE ARTHROSCOPY'	(b) (4), (b) (6)	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	(b) (4), (b) (6)	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	(b) (4), (b) (6)	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2008'	System	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2008'	System	01 Sep 2020 18:00:21

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:01

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4)	01 Sep 2020 18:02:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:02:52
Data point term sent to Coder	System	01 Sep 2020 18:01:26
User entered 'SURGERY - VASECTOMY'	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2014'	(b) (4), (b) (6)	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2014'	(b) (4), (b) (6)	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2014'	System	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '2014'	System	01 Sep 2020 18:00:41

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '10:25'	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1 Sep 2020 10:25'	System	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Height (xxx.x)

Audit	User	Time (GMT)
User entered '187.0' cm	(b) (4), (b) (6)	01 Sep 2020 18:01:58
DataPoint set to visible.	System	01 Sep 2020 16:23:02

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '110.0' kg	(b) (4), (b) (6)	01 Sep 2020 18:01:58
DataPoint set to visible.	System	01 Sep 2020 16:23:02

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '31.45643'	System	01 Sep 2020 18:01:58
DataPoint set to visible.	System	01 Sep 2020 16:23:02

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	01 Sep 2020 18:01:58
DataPoint set to visible.	System	01 Sep 2020 16:23:02

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 18:01:58

US3352299

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:02:06

US3352299

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:02:06

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

[Specify](#)

Audit	User	Time (GMT)
User entered 'GOES TO SHOP AND RESTAURANT'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:01

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:02:52

US3352299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:03:10

US3352299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:03:10

US3352299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 18:03:10

US3352299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	01 Sep 2020 18:03:10

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	01 Sep 2020 15:34:32

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:01

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '110587'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	01 Sep 2020 15:34:32

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 15:34:32

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:03:30

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:03:30

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:01

Severe obesity (body mass index \geq 40kg/m²)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:03:30

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:01

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:03:30

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:01

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:03:30

US3352299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	Wanda Delgado (b) (4)	02 Nov 2020 17:59:26
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:54:03
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:54:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:01

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:01

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '10:25'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1 Sep 2020 10:25'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '45'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '15'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '134'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:01

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
Query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' canceled (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 21:48:40
User opened query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:51:45
User entered '12:14'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1 Sep 2020 12:14'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.5' C	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 09:08:37
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'VITAL SIGNS REPEATED AND RECORDED UNDER UNSCHEDULED VITAL SIGNS' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:17:28
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Sep 2020 18:05:02
User entered '44'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '131'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '83'	(b) (4), (b) (6)	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 18:05:02

US3352299

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:05:42

US3352299

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:05:42

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

What was the treatment date? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '11:44'	(b) (4), (b) (6)	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1 Sep 2020 11:44'	System	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 16:23:24

US3352299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:06:10

US3352299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:06:10

US3352299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:27'	(b) (4), (b) (6)	01 Sep 2020 18:06:10

US3352299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1 Sep 2020 11:27'	System	01 Sep 2020 18:06:10

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:11'	(b) (4), (b) (6)	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '1 Sep 2020 11:11'	System	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:06:22

US3352299

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:06:27

US3352299

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:06:27

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:23:52', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '75da0372-0a2d-4ae1-8bf8-220d7adc1688'	System	01 Sep 2020 16:24:15
User entered 'Yes (Y)'	System	01 Sep 2020 16:24:15

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:02', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '75da0372-0a2d-4ae1-8bf8-220d7adc1688' User entered '96.1'	System	01 Sep 2020 16:24:15
	System	01 Sep 2020 16:24:15

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:06', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '75da0372-0a2d-4ae1-8bf8-220d7adc1688'	System	01 Sep 2020 16:24:15
User entered 'No (N)'	System	01 Sep 2020 16:24:15

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:11', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '75da0372-0a2d-4ae1-8bf8-220d7adc1688'	System	01 Sep 2020 16:24:15
User entered '01 Sep 2020 12:24'	System	01 Sep 2020 16:24:15

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:04'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 14:34'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:11:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0a73e54b-76e3-4b69-af6f-75f7f261ce81' User entered 'Yes (Y)'	System	02 Sep 2020 01:12:01

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:11:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0a73e54b-76e3-4b69-af6f-75f7f261ce81'	System	02 Sep 2020 01:12:01
User entered '97.7'	System	02 Sep 2020 01:12:01

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:11:54', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0a73e54b-76e3-4b69-af6f-75f7f261ce81'	System	02 Sep 2020 01:12:01
User entered 'No (N)'	System	02 Sep 2020 01:12:01

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:11:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0a73e54b-76e3-4b69-af6f-75f7f261ce81'	System	02 Sep 2020 01:12:01
User entered '01 Sep 2020 21:11'	System	02 Sep 2020 01:12:01

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:29'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 2'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:32:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b0b834c7-4466-47c6-b9b1-1ad3b7154807'	System	03 Sep 2020 02:33:29
User entered 'Yes (Y)'	System	03 Sep 2020 02:33:29

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b0b834c7-4466-47c6-b9b1-1ad3b7154807'	System	03 Sep 2020 02:33:29
User entered '96.3'	System	03 Sep 2020 02:33:29

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:22', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b0b834c7-4466-47c6-b9b1-1ad3b7154807'	System	03 Sep 2020 02:33:29
User entered 'No (N)'	System	03 Sep 2020 02:33:29

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:26', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b0b834c7-4466-47c6-b9b1-1ad3b7154807'	System	03 Sep 2020 02:33:29
User entered '02 Sep 2020 22:33'	System	03 Sep 2020 02:33:29

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 3'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a57ba51b-ad1e-4fab-bad3-1592ea4bd560'	System	03 Sep 2020 23:26:24
User entered 'Yes (Y)'	System	03 Sep 2020 23:26:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:15', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a57ba51b-ad1e-4fab-bad3-1592ea4bd560'	System	03 Sep 2020 23:26:24
User entered '97.2'	System	03 Sep 2020 23:26:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a57ba51b-ad1e-4fab-bad3-1592ea4bd560'	System	03 Sep 2020 23:26:24
User entered 'No (N)'	System	03 Sep 2020 23:26:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a57ba51b-ad1e-4fab-bad3-1592ea4bd560'	System	03 Sep 2020 23:26:24
User entered '03 Sep 2020 19:26'	System	03 Sep 2020 23:26:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 4'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '2c851465-185a-4681-8bd2-18a4e8f9a2c0'	System	05 Sep 2020 12:18:41
User entered 'Yes (Y)'	System	05 Sep 2020 12:18:41

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:18:31', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '2c851465-185a-4681-8bd2-18a4e8f9a2c0'	System	05 Sep 2020 12:18:41
User entered '96.2'	System	05 Sep 2020 12:18:41

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:18:34', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '2c851465-185a-4681-8bd2-18a4e8f9a2c0'	System	05 Sep 2020 12:18:41
User entered 'No (N)'	System	05 Sep 2020 12:18:41

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:18:37', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '2c851465-185a-4681-8bd2-18a4e8f9a2c0'	System	05 Sep 2020 12:18:41
User entered '05 Sep 2020 08:18'	System	05 Sep 2020 12:18:41

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 5'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:25:04', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '284738ff-c0a3-4b9a-8743-75daa0d84a3e'	System	06 Sep 2020 02:25:17
User entered 'Yes (Y)'	System	06 Sep 2020 02:25:17

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:25:08', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '284738ff-c0a3-4b9a-8743-75daa0d84a3e' User entered '97.5'	System	06 Sep 2020 02:25:17

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:25:11', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '284738ff-c0a3-4b9a-8743-75daa0d84a3e'	System	06 Sep 2020 02:25:17
User entered 'No (N)'	System	06 Sep 2020 02:25:17

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:25:14', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '284738ff-c0a3-4b9a-8743-75daa0d84a3e'	System	06 Sep 2020 02:25:17
User entered '05 Sep 2020 22:25'	System	06 Sep 2020 02:25:17

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 6'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:22:43', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f48ffdb3-42e5-4f6d-87f5-a7ab51b4b24a'	System	07 Sep 2020 02:22:56
User entered 'Yes (Y)'	System	07 Sep 2020 02:22:56

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:22:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f48ffdb3-42e5-4f6d-87f5-a7ab51b4b24a' User entered '97.1'	System	07 Sep 2020 02:22:56
	System	07 Sep 2020 02:22:56

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:22:51', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f48ffdb3-42e5-4f6d-87f5-a7ab51b4b24a'	System	07 Sep 2020 02:22:56
User entered 'No (N)'	System	07 Sep 2020 02:22:56

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:22:53', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f48ffdb3-42e5-4f6d-87f5-a7ab51b4b24a' User entered '06 Sep 2020 22:22'	System	07 Sep 2020 02:22:56
	System	07 Sep 2020 02:22:56

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 7'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b93c992-7bbe-49d1-a1b2-a277a52cdee2'	System	08 Sep 2020 02:36:40
User entered 'Yes (Y)'	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b93c992-7bbe-49d1-a1b2-a277a52cdee2'	System	08 Sep 2020 02:36:40
User entered '96.8'	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:31', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b93c992-7bbe-49d1-a1b2-a277a52cdee2'	System	08 Sep 2020 02:36:40
User entered 'No (N)'	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:34', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b93c992-7bbe-49d1-a1b2-a277a52cdee2'	System	08 Sep 2020 02:36:40
User entered '07 Sep 2020 22:36'	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1f2e9368-bb18-4892-931f-b299566a570b'	System	01 Sep 2020 16:24:53
User entered 'None (1)'	System	01 Sep 2020 16:24:53

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1f2e9368-bb18-4892-931f-b299566a570b'	System	01 Sep 2020 16:24:53
User entered 'No (N)'	System	01 Sep 2020 16:24:53

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:40', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1f2e9368-bb18-4892-931f-b299566a570b'	System	01 Sep 2020 16:24:53
User entered 'No (N)'	System	01 Sep 2020 16:24:53

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1f2e9368-bb18-4892-931f-b299566a570b'	System	01 Sep 2020 16:24:53
User entered 'None (1)'	System	01 Sep 2020 16:24:53

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1f2e9368-bb18-4892-931f-b299566a570b'	System	01 Sep 2020 16:24:53
User entered '01 Sep 2020 12:24'	System	01 Sep 2020 16:24:53

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:04'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 14:34'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:12:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'c144d588-5d53-4ec9-a2ed-77dd7d490af4'	System	02 Sep 2020 01:14:27
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 01:14:27

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:12:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'c144d588-5d53-4ec9-a2ed-77dd7d490af4'	System	02 Sep 2020 01:14:27
User entered 'No (N)'	System	02 Sep 2020 01:14:27

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:11', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'c144d588-5d53-4ec9-a2ed-77dd7d490af4'	System	02 Sep 2020 01:14:27
User entered 'No (N)'	System	02 Sep 2020 01:14:27

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'c144d588-5d53-4ec9-a2ed-77dd7d490af4' User entered 'None (1)'	System	02 Sep 2020 01:14:27
	System	02 Sep 2020 01:14:27

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:26', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'c144d588-5d53-4ec9-a2ed-77dd7d490af4'	System	02 Sep 2020 01:14:27
User entered '01 Sep 2020 21:14'	System	02 Sep 2020 01:14:27

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:29'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 2'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:31', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '26282362-6f12-436c-bf74-e84254fa40a5'	System	03 Sep 2020 02:33:43
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 02:33:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:34', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '26282362-6f12-436c-bf74-e84254fa40a5'	System	03 Sep 2020 02:33:43
User entered 'No (N)'	System	03 Sep 2020 02:33:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '26282362-6f12-436c-bf74-e84254fa40a5'	System	03 Sep 2020 02:33:43
User entered 'No (N)'	System	03 Sep 2020 02:33:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:39', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '26282362-6f12-436c-bf74-e84254fa40a5'	System	03 Sep 2020 02:33:43
User entered 'None (1)'	System	03 Sep 2020 02:33:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:42', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '26282362-6f12-436c-bf74-e84254fa40a5'	System	03 Sep 2020 02:33:43
User entered '02 Sep 2020 22:33'	System	03 Sep 2020 02:33:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 3'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:29', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a22842f5-6a6f-4598-9015-8301e1d29fcb'	System	03 Sep 2020 23:26:43
User entered 'None (1)'	System	03 Sep 2020 23:26:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:32', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a22842f5-6a6f-4598-9015-8301e1d29fcb'	System	03 Sep 2020 23:26:43
User entered 'No (N)'	System	03 Sep 2020 23:26:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:34', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a22842f5-6a6f-4598-9015-8301e1d29fcb'	System	03 Sep 2020 23:26:43
User entered 'No (N)'	System	03 Sep 2020 23:26:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:38', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a22842f5-6a6f-4598-9015-8301e1d29fcb'	System	03 Sep 2020 23:26:43
User entered 'None (1)'	System	03 Sep 2020 23:26:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:41', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a22842f5-6a6f-4598-9015-8301e1d29fcb'	System	03 Sep 2020 23:26:43
User entered '03 Sep 2020 19:26'	System	03 Sep 2020 23:26:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 4'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'aa965510-db9a-41c2-bc50-6a6235009af5'	System	05 Sep 2020 12:17:43
User entered 'None (1)'	System	05 Sep 2020 12:17:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:32', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'aa965510-db9a-41c2-bc50-6a6235009af5'	System	05 Sep 2020 12:17:43
User entered 'No (N)'	System	05 Sep 2020 12:17:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:34', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'aa965510-db9a-41c2-bc50-6a6235009af5'	System	05 Sep 2020 12:17:43
User entered 'No (N)'	System	05 Sep 2020 12:17:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:38', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'aa965510-db9a-41c2-bc50-6a6235009af5'	System	05 Sep 2020 12:17:43
User entered 'None (1)'	System	05 Sep 2020 12:17:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:42', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'aa965510-db9a-41c2-bc50-6a6235009af5'	System	05 Sep 2020 12:17:43
User entered '05 Sep 2020 08:17'	System	05 Sep 2020 12:17:43

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 5'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd3710611-bd3f-47d4-92e3-c0e2e71b2a6e'	System	06 Sep 2020 02:25:02
User entered 'None (1)'	System	06 Sep 2020 02:25:02

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:39', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd3710611-bd3f-47d4-92e3-c0e2e71b2a6e'	System	06 Sep 2020 02:25:02
User entered 'No (N)'	System	06 Sep 2020 02:25:02

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:52', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd3710611-bd3f-47d4-92e3-c0e2e71b2a6e'	System	06 Sep 2020 02:25:02
User entered 'No (N)'	System	06 Sep 2020 02:25:02

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd3710611-bd3f-47d4-92e3-c0e2e71b2a6e'	System	06 Sep 2020 02:25:02
User entered 'None (1)'	System	06 Sep 2020 02:25:02

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:58', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd3710611-bd3f-47d4-92e3-c0e2e71b2a6e'	System	06 Sep 2020 02:25:02
User entered '05 Sep 2020 22:24'	System	06 Sep 2020 02:25:02

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 6'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:22:57', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1b8bd912-1b47-4a0c-a79e-de1c7f52185d' User entered 'None (1)'	System	07 Sep 2020 02:23:07
	System	07 Sep 2020 02:23:07

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:22:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1b8bd912-1b47-4a0c-a79e-de1c7f52185d'	System	07 Sep 2020 02:23:07
User entered 'No (N)'	System	07 Sep 2020 02:23:07

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:01', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1b8bd912-1b47-4a0c-a79e-de1c7f52185d'	System	07 Sep 2020 02:23:07
User entered 'No (N)'	System	07 Sep 2020 02:23:07

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:03', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1b8bd912-1b47-4a0c-a79e-de1c7f52185d' User entered 'None (1)'	System	07 Sep 2020 02:23:07
	System	07 Sep 2020 02:23:07

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:05', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1b8bd912-1b47-4a0c-a79e-de1c7f52185d' User entered '06 Sep 2020 22:23'	System	07 Sep 2020 02:23:07
	System	07 Sep 2020 02:23:07

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 7'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c0f8ddc-319b-41ca-ba11-9bb6969c4311'	System	08 Sep 2020 02:36:40
User entered 'None (1)'	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:02', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c0f8ddc-319b-41ca-ba11-9bb6969c4311'	System	08 Sep 2020 02:36:40
User entered 'No (N)'	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:05', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c0f8ddc-319b-41ca-ba11-9bb6969c4311' User entered 'No (N)'	System	08 Sep 2020 02:36:40
	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:08', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c0f8ddc-319b-41ca-ba11-9bb6969c4311' User entered 'None (1)'	System	08 Sep 2020 02:36:40
	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:36:12', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c0f8ddc-319b-41ca-ba11-9bb6969c4311'	System	08 Sep 2020 02:36:40
User entered '07 Sep 2020 22:36'	System	08 Sep 2020 02:36:40

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:24:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'None (0)'	System	01 Sep 2020 16:25:39

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'None (0)'	System	01 Sep 2020 16:25:39

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:14', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'None (0)'	System	01 Sep 2020 16:25:39

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:17', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'None (0)'	System	01 Sep 2020 16:25:39

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:19', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'None (0)'	System	01 Sep 2020 16:25:39

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:22', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'None (0)'	System	01 Sep 2020 16:25:39

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:33', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered 'No (N)'	System	01 Sep 2020 16:25:39

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T12:25:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1381893e-ac8a-4e74-82c3-ae9d9fa5d413'	System	01 Sep 2020 16:25:39
User entered '01 Sep 2020 12:25'	System	01 Sep 2020 16:25:39

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:04'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 14:34'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'None (0)'	System	02 Sep 2020 01:14:53

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:32', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'None (0)'	System	02 Sep 2020 01:14:53

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'None (0)'	System	02 Sep 2020 01:14:53

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:38', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'None (0)'	System	02 Sep 2020 01:14:53

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:40', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'None (0)'	System	02 Sep 2020 01:14:53

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:42', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'None (0)'	System	02 Sep 2020 01:14:53

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:49', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered 'No (N)'	System	02 Sep 2020 01:14:53

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-01T21:14:51', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4513ad0f-018c-4169-ae22-1b174cfaf9ec'	System	02 Sep 2020 01:14:53
User entered '01 Sep 2020 21:14'	System	02 Sep 2020 01:14:53

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:29'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 2'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a'	System	03 Sep 2020 02:33:59
User entered 'None (0)'	System	03 Sep 2020 02:33:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a' User entered 'None (0)'	System	03 Sep 2020 02:33:59
	System	03 Sep 2020 02:33:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:49', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a'	System	03 Sep 2020 02:33:59
User entered 'None (0)'	System	03 Sep 2020 02:33:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a'	System	03 Sep 2020 02:33:59
User entered 'None (0)'	System	03 Sep 2020 02:33:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:52', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a'	System	03 Sep 2020 02:33:59
User entered 'None (0)'	System	03 Sep 2020 02:33:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:54', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a' User entered 'None (0)'	System	03 Sep 2020 02:33:59
	System	03 Sep 2020 02:33:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:56', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a'	System	03 Sep 2020 02:33:59
User entered 'No (N)'	System	03 Sep 2020 02:33:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-02T22:33:58', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '00298c96-48e8-486a-bc6f-3e1c3939e95a' User entered '02 Sep 2020 22:33'	System	03 Sep 2020 02:33:59
	System	03 Sep 2020 02:33:59

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 3'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered 'None (0)'	System	03 Sep 2020 23:27:09

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered 'None (0)'	System	03 Sep 2020 23:27:09

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:51', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered 'None (0)'	System	03 Sep 2020 23:27:09

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349' User entered 'None (0)'	System	03 Sep 2020 23:27:09
	System	03 Sep 2020 23:27:09

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:26:58', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered 'None (0)'	System	03 Sep 2020 23:27:09

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:27:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered 'None (0)'	System	03 Sep 2020 23:27:09

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:27:04', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349'	System	03 Sep 2020 23:27:09
User entered 'No (N)'	System	03 Sep 2020 23:27:09

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-03T19:27:06', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a71affcf-a7af-4587-a157-3e1166d78349' User entered '03 Sep 2020 19:27'	System	03 Sep 2020 23:27:09
	System	03 Sep 2020 23:27:09

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 4'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:05', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'None (0)'	System	05 Sep 2020 12:17:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:07', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'None (0)'	System	05 Sep 2020 12:17:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:09', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'None (0)'	System	05 Sep 2020 12:17:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:14', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'None (0)'	System	05 Sep 2020 12:17:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:16', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'None (0)'	System	05 Sep 2020 12:17:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'None (0)'	System	05 Sep 2020 12:17:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered 'No (N)'	System	05 Sep 2020 12:17:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T08:17:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '90ae032e-de0d-4d39-be77-2544633affd5'	System	05 Sep 2020 12:17:24
User entered '05 Sep 2020 08:17'	System	05 Sep 2020 12:17:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 5'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:11', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'None (0)'	System	06 Sep 2020 02:24:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:13', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'None (0)'	System	06 Sep 2020 02:24:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:15', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'None (0)'	System	06 Sep 2020 02:24:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:16', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'None (0)'	System	06 Sep 2020 02:24:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'None (0)'	System	06 Sep 2020 02:24:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:24', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'None (0)'	System	06 Sep 2020 02:24:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:29', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered 'No (N)'	System	06 Sep 2020 02:24:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-05T22:24:31', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5c239e64-733f-4337-aec8-73a05031f580'	System	06 Sep 2020 02:24:36
User entered '05 Sep 2020 22:24'	System	06 Sep 2020 02:24:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 6'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:16', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'None (0)'	System	07 Sep 2020 02:24:07

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'None (0)'	System	07 Sep 2020 02:24:07

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'None (0)'	System	07 Sep 2020 02:24:07

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:40', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'None (0)'	System	07 Sep 2020 02:24:07

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:42', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'None (0)'	System	07 Sep 2020 02:24:07

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:23:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'None (0)'	System	07 Sep 2020 02:24:07

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:24:01', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered 'No (N)'	System	07 Sep 2020 02:24:07

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-06T22:24:04', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd23e5829-7cec-4544-bfa7-3456ce1add98'	System	07 Sep 2020 02:24:07
User entered '06 Sep 2020 22:24'	System	07 Sep 2020 02:24:07

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 7'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:33', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'None (0)'	System	08 Sep 2020 02:36:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:35', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'None (0)'	System	08 Sep 2020 02:36:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:38', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'None (0)'	System	08 Sep 2020 02:36:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:42', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'None (0)'	System	08 Sep 2020 02:36:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'None (0)'	System	08 Sep 2020 02:36:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'None (0)'	System	08 Sep 2020 02:36:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:52', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered 'No (N)'	System	08 Sep 2020 02:36:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-07T22:35:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '1a0faf01-c85c-4a67-9122-d8f0260f4876'	System	08 Sep 2020 02:36:36
User entered '07 Sep 2020 22:35'	System	08 Sep 2020 02:36:36

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:23:24

US3352299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 19:34:15

US3352299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 19:34:15

US3352299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 19:34:15

US3352299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 19:34:15

US3352299

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 19:34:28

US3352299

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 19:34:28

US3352299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 19:27:31

US3352299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 19:27:31

US3352299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 19:27:31

US3352299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 19:27:31

US3352299

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 19:27:37

US3352299

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Sep 2020 19:27:37

US3352299

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:14

US3352299

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Sep 2020 14:10:14

US3352299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	29 Sep 2020 15:05:41
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Wanda Delgado (b) (4)	29 Sep 2020 15:05:41
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Wanda Delgado (b) (4)	29 Sep 2020 15:05:41
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	29 Sep 2020 15:05:41

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wanda Delgado (b) (4) (b) (4) (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '09:10'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '29 Sep 2020 09:10'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Wanda Delgado (b) (4) (b) (4) (b) (4)	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '56'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '14'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '129'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '83'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '10:25'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '29 Sep 2020 10:25'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '51'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '13'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '125'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	Wanda Delgado (b) (4)	29 Sep 2020 15:06:54
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 15:06:54

US3352299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Wanda Delgado (b) (4) (b) (4) (b) (4)	29 Sep 2020 15:07:24

US3352299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Wanda Delgado (b) (4)	29 Sep 2020 15:07:24
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '09:55'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '29 Sep 2020 09:55'	System	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 14:10:46

US3352299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:39
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:39
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:29'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:39
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '29 Sep 2020 09:29'	System	29 Sep 2020 15:07:39

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:56
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Wanda Delgado (b) (4) (b) (4) (b) (4)	29 Sep 2020 15:07:56

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:56
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:24'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:56
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered '29 Sep 2020 09:24'	System	29 Sep 2020 15:07:56

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:56
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Wanda Delgado (b) (4)	29 Sep 2020 15:07:56
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Wanda Delgado (b) (4)	29 Sep 2020 15:07:56
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 15:07:56

US3352299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	29 Sep 2020 15:08:03
	(b) (4)	

US3352299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Sep 2020 15:08:03

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:31', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6accf5eb-db54-4755-89de-e289205c560b'	System	29 Sep 2020 14:28:45
User entered 'Yes (Y)'	System	29 Sep 2020 14:28:45

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:35', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6accf5eb-db54-4755-89de-e289205c560b' User entered '98.3'	System	29 Sep 2020 14:28:45
	System	29 Sep 2020 14:28:45

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:39', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6accf5eb-db54-4755-89de-e289205c560b'	System	29 Sep 2020 14:28:45
User entered 'No (N)'	System	29 Sep 2020 14:28:45

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:42', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '6accf5eb-db54-4755-89de-e289205c560b' User entered '29 Sep 2020 10:28'	System	29 Sep 2020 14:28:45
	System	29 Sep 2020 14:28:45

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 10:15'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:45'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:03', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '3c34a680-9ac9-4e03-b1e6-08e69ab31130'	System	29 Sep 2020 23:37:15
User entered 'Yes (Y)'	System	29 Sep 2020 23:37:15

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:07', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '3c34a680-9ac9-4e03-b1e6-08e69ab31130' User entered '96.2'	System	29 Sep 2020 23:37:15
	System	29 Sep 2020 23:37:15

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '3c34a680-9ac9-4e03-b1e6-08e69ab31130'	System	29 Sep 2020 23:37:15
User entered 'No (N)'	System	29 Sep 2020 23:37:15

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:13', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '3c34a680-9ac9-4e03-b1e6-08e69ab31130' User entered '29 Sep 2020 19:37'	System	29 Sep 2020 23:37:15
	System	29 Sep 2020 23:37:15

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 13:40'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 2'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:22', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a65cf7e2-380e-459e-93ea-345b5d0c89e8'	System	30 Sep 2020 22:53:36
User entered 'Yes (Y)'	System	30 Sep 2020 22:53:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a65cf7e2-380e-459e-93ea-345b5d0c89e8'	System	30 Sep 2020 22:53:36
User entered '101.0'	System	30 Sep 2020 22:53:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a65cf7e2-380e-459e-93ea-345b5d0c89e8'	System	30 Sep 2020 22:53:36
User entered 'No (N)'	System	30 Sep 2020 22:53:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:35', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'a65cf7e2-380e-459e-93ea-345b5d0c89e8' User entered '30 Sep 2020 18:53'	System	30 Sep 2020 22:53:36
	System	30 Sep 2020 22:53:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 3'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:27:48', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7a323f96-8e74-44b7-801a-8a320b970e8a' User entered 'Yes (Y)'	System	02 Oct 2020 00:28:02

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:27:53', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7a323f96-8e74-44b7-801a-8a320b970e8a' User entered '98.2'	System	02 Oct 2020 00:28:02

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:27:56', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7a323f96-8e74-44b7-801a-8a320b970e8a'	System	02 Oct 2020 00:28:02
User entered 'No (N)'	System	02 Oct 2020 00:28:02

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:27:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7a323f96-8e74-44b7-801a-8a320b970e8a' User entered '01 Oct 2020 20:27'	System	02 Oct 2020 00:28:02
	System	02 Oct 2020 00:28:02

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 4'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5bc60b06-7b90-46dc-8208-141ce1a286cd' User entered 'Yes (Y)'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:24', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5bc60b06-7b90-46dc-8208-141ce1a286cd' User entered '98.2'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5bc60b06-7b90-46dc-8208-141ce1a286cd'	System	03 Oct 2020 16:13:44
User entered 'No (N)'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5bc60b06-7b90-46dc-8208-141ce1a286cd' User entered '03 Oct 2020 06:52'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 5'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:12:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4e1aa54e-61fb-474c-bf20-fc2c6f51c4e4'	System	03 Oct 2020 16:13:48
User entered 'Yes (Y)'	System	03 Oct 2020 16:13:48

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:12:53', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4e1aa54e-61fb-474c-bf20-fc2c6f51c4e4'	System	03 Oct 2020 16:13:48
User entered '97.9'	System	03 Oct 2020 16:13:48

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:12:56', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4e1aa54e-61fb-474c-bf20-fc2c6f51c4e4'	System	03 Oct 2020 16:13:48
User entered 'No (N)'	System	03 Oct 2020 16:13:48

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:12:58', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '4e1aa54e-61fb-474c-bf20-fc2c6f51c4e4'	System	03 Oct 2020 16:13:48
User entered '03 Oct 2020 12:12'	System	03 Oct 2020 16:13:48

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 6'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:01:40', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'bfc16047-6df7-411a-9892-339abdcff4e5'	System	05 Oct 2020 11:01:53
User entered 'Yes (Y)'	System	05 Oct 2020 11:01:53

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:01:44', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'bfc16047-6df7-411a-9892-339abdcff4e5'	System	05 Oct 2020 11:01:53
User entered '97.6'	System	05 Oct 2020 11:01:53

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:01:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'bfc16047-6df7-411a-9892-339abdcff4e5'	System	05 Oct 2020 11:01:53
User entered 'No (N)'	System	05 Oct 2020 11:01:53

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:01:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'bfc16047-6df7-411a-9892-339abdcff4e5' User entered '05 Oct 2020 07:01'	System	05 Oct 2020 11:01:53
	System	05 Oct 2020 11:01:53

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 7'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:34:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b35ddfb-83b3-48dd-bb24-0bf203e8f6cb' User entered 'Yes (Y)'	System	05 Oct 2020 21:35:36
	System	05 Oct 2020 21:35:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:34:51', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b35ddfb-83b3-48dd-bb24-0bf203e8f6cb' User entered '98.2'	System	05 Oct 2020 21:35:36
	System	05 Oct 2020 21:35:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:35:14', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b35ddfb-83b3-48dd-bb24-0bf203e8f6cb'	System	05 Oct 2020 21:35:36
User entered 'No (N)'	System	05 Oct 2020 21:35:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:35:26', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7b35ddfb-83b3-48dd-bb24-0bf203e8f6cb' User entered '05 Oct 2020 17:35'	System	05 Oct 2020 21:35:36
	System	05 Oct 2020 21:35:36

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8f3d0fa9-b3c3-40d8-b9b7-87e274a8fde2'	System	29 Sep 2020 14:29:02
User entered 'None (1)'	System	29 Sep 2020 14:29:02

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8f3d0fa9-b3c3-40d8-b9b7-87e274a8fde2'	System	29 Sep 2020 14:29:02
User entered 'No (N)'	System	29 Sep 2020 14:29:02

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:52', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8f3d0fa9-b3c3-40d8-b9b7-87e274a8fde2'	System	29 Sep 2020 14:29:02
User entered 'No (N)'	System	29 Sep 2020 14:29:02

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:56', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8f3d0fa9-b3c3-40d8-b9b7-87e274a8fde2'	System	29 Sep 2020 14:29:02
User entered 'None (1)'	System	29 Sep 2020 14:29:02

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:28:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8f3d0fa9-b3c3-40d8-b9b7-87e274a8fde2'	System	29 Sep 2020 14:29:02
User entered '29 Sep 2020 10:28'	System	29 Sep 2020 14:29:02

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 10:15'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:45'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:24', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b1ae49b2-cd73-42b1-bbab-e0b08e77e168'	System	29 Sep 2020 23:37:59
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 23:37:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b1ae49b2-cd73-42b1-bbab-e0b08e77e168'	System	29 Sep 2020 23:37:59
User entered 'No (N)'	System	29 Sep 2020 23:37:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:44', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b1ae49b2-cd73-42b1-bbab-e0b08e77e168'	System	29 Sep 2020 23:37:59
User entered 'No (N)'	System	29 Sep 2020 23:37:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:53', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b1ae49b2-cd73-42b1-bbab-e0b08e77e168'	System	29 Sep 2020 23:37:59
User entered 'None (1)'	System	29 Sep 2020 23:37:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:37:56', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'b1ae49b2-cd73-42b1-bbab-e0b08e77e168' User entered '29 Sep 2020 19:37'	System	29 Sep 2020 23:37:59
	System	29 Sep 2020 23:37:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 13:40'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 2'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:41', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5b1c44bd-2f50-4216-9f87-3f0f923348cf' User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 22:53:58
	System	30 Sep 2020 22:53:58

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:43', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5b1c44bd-2f50-4216-9f87-3f0f923348cf' User entered 'No (N)'	System	30 Sep 2020 22:53:58

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:46', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5b1c44bd-2f50-4216-9f87-3f0f923348cf' User entered 'No (N)'	System	30 Sep 2020 22:53:58

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:51', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5b1c44bd-2f50-4216-9f87-3f0f923348cf' User entered 'None (1)'	System	30 Sep 2020 22:53:58
	System	30 Sep 2020 22:53:58

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:53:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '5b1c44bd-2f50-4216-9f87-3f0f923348cf' User entered '30 Sep 2020 18:53'	System	30 Sep 2020 22:53:58
	System	30 Sep 2020 22:53:58

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 3'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:06', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '43124511-99b1-4d71-9cfa-6d60ae32d294'	System	02 Oct 2020 00:28:18
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 00:28:18

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:08', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '43124511-99b1-4d71-9cfa-6d60ae32d294'	System	02 Oct 2020 00:28:18
User entered 'No (N)'	System	02 Oct 2020 00:28:18

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:11', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '43124511-99b1-4d71-9cfa-6d60ae32d294'	System	02 Oct 2020 00:28:18
User entered 'No (N)'	System	02 Oct 2020 00:28:18

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:15', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '43124511-99b1-4d71-9cfa-6d60ae32d294'	System	02 Oct 2020 00:28:18
User entered 'None (1)'	System	02 Oct 2020 00:28:18

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:17', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '43124511-99b1-4d71-9cfa-6d60ae32d294'	System	02 Oct 2020 00:28:18
User entered '01 Oct 2020 20:28'	System	02 Oct 2020 00:28:18

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 4'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:38', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '68b7e188-6817-4dc2-9d3e-795fffdac77'	System	03 Oct 2020 16:13:44
User entered 'None (1)'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:41', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '68b7e188-6817-4dc2-9d3e-795fffdac77'	System	03 Oct 2020 16:13:44
User entered 'No (N)'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:43', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '68b7e188-6817-4dc2-9d3e-795ffdaec77'	System	03 Oct 2020 16:13:44
User entered 'No (N)'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '68b7e188-6817-4dc2-9d3e-795fffdac77'	System	03 Oct 2020 16:13:44
User entered 'None (1)'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:48', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '68b7e188-6817-4dc2-9d3e-795fffaec77'	System	03 Oct 2020 16:13:44
User entered '03 Oct 2020 06:52'	System	03 Oct 2020 16:13:44

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 5'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:07', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8c04e52c-04e1-431d-842c-3d94d5db4d9a'	System	03 Oct 2020 16:13:59
User entered 'None (1)'	System	03 Oct 2020 16:13:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:06', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8c04e52c-04e1-431d-842c-3d94d5db4d9a'	System	03 Oct 2020 16:13:59
User entered 'No (N)'	System	03 Oct 2020 16:13:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8c04e52c-04e1-431d-842c-3d94d5db4d9a'	System	03 Oct 2020 16:13:59
User entered 'No (N)'	System	03 Oct 2020 16:13:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:12', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8c04e52c-04e1-431d-842c-3d94d5db4d9a'	System	03 Oct 2020 16:13:59
User entered 'None (1)'	System	03 Oct 2020 16:13:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:14', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '8c04e52c-04e1-431d-842c-3d94d5db4d9a'	System	03 Oct 2020 16:13:59
User entered '03 Oct 2020 12:13'	System	03 Oct 2020 16:13:59

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 6'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:01:54', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7d2f8537-40c8-4532-956b-32630004e37e'	System	05 Oct 2020 11:02:08
User entered 'None (1)'	System	05 Oct 2020 11:02:08

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:01:56', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7d2f8537-40c8-4532-956b-32630004e37e' User entered 'No (N)'	System	05 Oct 2020 11:02:08

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7d2f8537-40c8-4532-956b-32630004e37e'	System	05 Oct 2020 11:02:08
User entered 'No (N)'	System	05 Oct 2020 11:02:08

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:02', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7d2f8537-40c8-4532-956b-32630004e37e'	System	05 Oct 2020 11:02:08
User entered 'None (1)'	System	05 Oct 2020 11:02:08

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:04', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7d2f8537-40c8-4532-956b-32630004e37e' User entered '05 Oct 2020 07:02'	System	05 Oct 2020 11:02:08
	System	05 Oct 2020 11:02:08

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 7'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:35:51', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0598af45-c5f9-4158-a610-02c522fbb659'	System	05 Oct 2020 21:36:13
User entered 'None (1)'	System	05 Oct 2020 21:36:13

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:35:54', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0598af45-c5f9-4158-a610-02c522fbb659'	System	05 Oct 2020 21:36:13
User entered 'No (N)'	System	05 Oct 2020 21:36:13

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:02', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0598af45-c5f9-4158-a610-02c522fbb659'	System	05 Oct 2020 21:36:13
User entered 'No (N)'	System	05 Oct 2020 21:36:13

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:05', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0598af45-c5f9-4158-a610-02c522fbb659'	System	05 Oct 2020 21:36:13
User entered 'None (1)'	System	05 Oct 2020 21:36:13

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:11', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '0598af45-c5f9-4158-a610-02c522fbb659' User entered '05 Oct 2020 17:36'	System	05 Oct 2020 21:36:13
	System	05 Oct 2020 21:36:13

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:04', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'None (0)'	System	29 Sep 2020 14:29:22

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:06', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'None (0)'	System	29 Sep 2020 14:29:22

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:09', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'None (0)'	System	29 Sep 2020 14:29:22

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'None (0)'	System	29 Sep 2020 14:29:22

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:12', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'None (0)'	System	29 Sep 2020 14:29:22

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:13', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'None (0)'	System	29 Sep 2020 14:29:22

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:17', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered 'No (N)'	System	29 Sep 2020 14:29:22

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T10:29:19', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '12f74c9d-0e8d-4868-a53b-e78bf9067f40'	System	29 Sep 2020 14:29:22
User entered '29 Sep 2020 10:29'	System	29 Sep 2020 14:29:22

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 10:15'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:45'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:02', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'None (0)'	System	29 Sep 2020 23:38:24

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:05', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'None (0)'	System	29 Sep 2020 23:38:24

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:08', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'None (0)'	System	29 Sep 2020 23:38:24

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'None (0)'	System	29 Sep 2020 23:38:24

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:12', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'None (0)'	System	29 Sep 2020 23:38:24

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:15', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'No interference with activity (1)'	System	29 Sep 2020 23:38:24

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered 'No (N)'	System	29 Sep 2020 23:38:24

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-29T19:38:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '08d03193-fb2b-427e-af61-f8a039104293'	System	29 Sep 2020 23:38:24
User entered '29 Sep 2020 19:38'	System	29 Sep 2020 23:38:24

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 13:40'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 2'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered 'No interference with activity (1)'	System	30 Sep 2020 22:55:05

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:40', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered 'Some interference with activity (2)'	System	30 Sep 2020 22:55:05

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:45', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08' User entered 'None (0)'	System	30 Sep 2020 22:55:05
	System	30 Sep 2020 22:55:05

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:47', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered 'None (0)'	System	30 Sep 2020 22:55:05

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:50', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered 'None (0)'	System	30 Sep 2020 22:55:05

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered 'Some interference with activity not requiring medical attention (2)'	System	30 Sep 2020 22:55:05

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:54:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08'	System	30 Sep 2020 22:55:05
User entered 'No (N)'	System	30 Sep 2020 22:55:05

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-09-30T18:55:01', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '22a0b529-f254-4a56-9348-efd504fa9b08' User entered '30 Sep 2020 18:55'	System	30 Sep 2020 22:55:05
	System	30 Sep 2020 22:55:05

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 3'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:22', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eccc2'	System	02 Oct 2020 00:28:43
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:28:43

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:24', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eccc2'	System	02 Oct 2020 00:28:43
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:28:43

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eccc2'	System	02 Oct 2020 00:28:43
User entered 'None (0)'	System	02 Oct 2020 00:28:43

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:29', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eccc2'	System	02 Oct 2020 00:28:43
User entered 'None (0)'	System	02 Oct 2020 00:28:43

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:31', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eccc2'	System	02 Oct 2020 00:28:43
User entered 'None (0)'	System	02 Oct 2020 00:28:43

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:34', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eccc2'	System	02 Oct 2020 00:28:43
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:28:43

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eccc2'	System	02 Oct 2020 00:28:43
User entered 'No (N)'	System	02 Oct 2020 00:28:43

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-01T20:28:39', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '336f9d45-4b04-4852-94d9-6825eccc2'	System	02 Oct 2020 00:28:43
User entered '01 Oct 2020 20:28'	System	02 Oct 2020 00:28:43

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 4'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:55', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'None (0)'	System	03 Oct 2020 16:13:45

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:57', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'None (0)'	System	03 Oct 2020 16:13:45

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:52:59', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'None (0)'	System	03 Oct 2020 16:13:45

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:53:00', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'None (0)'	System	03 Oct 2020 16:13:45

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:53:02', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'None (0)'	System	03 Oct 2020 16:13:45

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:53:03', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'None (0)'	System	03 Oct 2020 16:13:45

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:53:05', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered 'No (N)'	System	03 Oct 2020 16:13:45

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T06:53:08', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd1724943-aa3a-4d0f-bf33-203f67f4d934'	System	03 Oct 2020 16:13:45
User entered '03 Oct 2020 06:53'	System	03 Oct 2020 16:13:45

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 5'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:20', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'No interference with activity (1)'	System	03 Oct 2020 16:14:11

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'No interference with activity (1)'	System	03 Oct 2020 16:14:11

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:25', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'None (0)'	System	03 Oct 2020 16:14:11

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'None (0)'	System	03 Oct 2020 16:14:11

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:29', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'None (0)'	System	03 Oct 2020 16:14:11

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'None (0)'	System	03 Oct 2020 16:14:11

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:33', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered 'No (N)'	System	03 Oct 2020 16:14:11

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-03T12:13:36', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'ed79f053-320d-461c-9066-2668cfcce91c'	System	03 Oct 2020 16:14:11
User entered '03 Oct 2020 12:13'	System	03 Oct 2020 16:14:11

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 6'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:08', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'None (0)'	System	05 Oct 2020 11:02:27

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:10', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'None (0)'	System	05 Oct 2020 11:02:27

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:12', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'None (0)'	System	05 Oct 2020 11:02:27

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:16', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'None (0)'	System	05 Oct 2020 11:02:27

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'None (0)'	System	05 Oct 2020 11:02:27

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:19', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'None (0)'	System	05 Oct 2020 11:02:27

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8'	System	05 Oct 2020 11:02:27
User entered 'No (N)'	System	05 Oct 2020 11:02:27

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T07:02:26', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'be483b46-07d4-4379-9762-4520863519c8' User entered '05 Oct 2020 07:02'	System	05 Oct 2020 11:02:27
	System	05 Oct 2020 11:02:27

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:10:46
User entered 'Day 7'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:25', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe'	System	05 Oct 2020 21:36:50
User entered 'None (0)'	System	05 Oct 2020 21:36:50

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:26', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe'	System	05 Oct 2020 21:36:50
User entered 'None (0)'	System	05 Oct 2020 21:36:50

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:32', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe' User entered 'None (0)'	System	05 Oct 2020 21:36:50
	System	05 Oct 2020 21:36:50

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:33', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe' User entered 'None (0)'	System	05 Oct 2020 21:36:50
	System	05 Oct 2020 21:36:50

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:37', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe' User entered 'None (0)'	System	05 Oct 2020 21:36:50

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:39', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe'	System	05 Oct 2020 21:36:50
User entered 'None (0)'	System	05 Oct 2020 21:36:50

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:44', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe'	System	05 Oct 2020 21:36:50
User entered 'No (N)'	System	05 Oct 2020 21:36:50

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-10-05T17:36:46', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'f67eddf5-54c1-494d-8312-9f108b79fefe' User entered '05 Oct 2020 17:36'	System	05 Oct 2020 21:36:50
	System	05 Oct 2020 21:36:50

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:10:46

US3352299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:10:46

US3352299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:44:31

US3352299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:44:31

US3352299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	06 Oct 2020 13:44:31

US3352299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:44:31

US3352299

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:44:36

US3352299

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 13:44:36

US3352299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:12:27

US3352299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 21:12:27

US3352299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 21:12:27

US3352299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 21:12:27

US3352299

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:12:31

US3352299

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Oct 2020 21:12:31

US3352299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 19:18:58

US3352299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 19:18:58

US3352299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 19:18:58

US3352299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:18:58

US3352299

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 19:19:35

US3352299

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Oct 2020 19:19:35

US3352299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:57:32

US3352299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:57:32

US3352299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:57:32

US3352299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	27 Oct 2020 13:57:32

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:16'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 09:16'	System	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '98'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '121'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '71'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 13:58:11

US3352299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:15

US3352299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:15

US3352299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:24

US3352299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:24

US3352299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:30'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:24

US3352299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 09:30'	System	27 Oct 2020 13:58:24

US3352299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Matthew Muniz (b) (4) (b) (4)	27 Oct 2020 13:58:27

US3352299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Oct 2020 13:58:27

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 64'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-01T07:34:25', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7ad5b9c4-be94-4d67-948f-ba752d305f4b'	System	01 Nov 2020 12:34:40
User entered 'No (N)'	System	01 Nov 2020 12:34:40

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-01T07:34:33', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7ad5b9c4-be94-4d67-948f-ba752d305f4b'	System	01 Nov 2020 12:34:40
User entered 'No (N)'	System	01 Nov 2020 12:34:40

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-01T07:34:37', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '7ad5b9c4-be94-4d67-948f-ba752d305f4b' User entered '01 Nov 2020 07:34:37'	System	01 Nov 2020 12:34:40
	System	01 Nov 2020 12:34:40

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 71'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-11T08:34:07', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd6fc9a5f-1cc4-4abf-9752-c8c65900743c'	System	11 Nov 2020 13:34:45
User entered 'Yes (Y)'	System	11 Nov 2020 13:34:45

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-11T08:34:13', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd6fc9a5f-1cc4-4abf-9752-c8c65900743c'	System	11 Nov 2020 13:34:45
User entered 'No (N)'	System	11 Nov 2020 13:34:45

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-11T08:34:18', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd6fc9a5f-1cc4-4abf-9752-c8c65900743c'	System	11 Nov 2020 13:34:45
User entered 'No (N)'	System	11 Nov 2020 13:34:45

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-11T08:34:24', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd6fc9a5f-1cc4-4abf-9752-c8c65900743c'	System	11 Nov 2020 13:34:45
User entered 'Yes (Y)'	System	11 Nov 2020 13:34:45

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEFE76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-11T08:34:32', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd6fc9a5f-1cc4-4abf-9752-c8c65900743c'	System	11 Nov 2020 13:34:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 13:34:45

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-11T08:34:35', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: 'd6fc9a5f-1cc4-4abf-9752-c8c65900743c' User entered '11 Nov 2020 08:34:35'	System	11 Nov 2020 13:34:45
	System	11 Nov 2020 13:34:45

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered 'Day 78'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-15T08:32:23', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '590b0f11-40d7-410e-bcb8-4b213057b18b'	System	15 Nov 2020 13:32:32
User entered 'No (N)'	System	15 Nov 2020 13:32:32

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-15T08:32:27', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '590b0f11-40d7-410e-bcb8-4b213057b18b'	System	15 Nov 2020 13:32:32
User entered 'No (N)'	System	15 Nov 2020 13:32:32

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15DEF76-0CAC-4F02-8D58-01AF2F1D0285)', Time: '2020-11-15T08:32:30', User OID: 'PatientReportedOutcome (US3352299)', ODM File OID: '590b0f11-40d7-410e-bcb8-4b213057b18b' User entered '15 Nov 2020 08:32:30'	System	15 Nov 2020 13:32:32
	System	15 Nov 2020 13:32:32

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 16:23:24

US3352299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:23:24
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 16:23:24

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:35:53

US3352299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:53
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:35:53

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 11:01:01

[Visit Date](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: if confirmed that form was added in error, then please consider deleting data and inactivating the page or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:04:08
Query 'Per CDM: if confirmed that form was added in error, then please consider deleting data and inactivating the page or comment accordingly. ' answered with 'not able to inactivate the pages ' (Site from DM).	Matthew Muniz (b) (4)	16 Oct 2020 20:14:10
User opened query 'Per CDM: if confirmed that form was added in error, then please consider deleting data and inactivating the page or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 18:43:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 18:43:39
Query 'Data is required. Please complete.' answered with 'entered in error ' (Site from System).	Matthew Muniz (b) (4)	15 Oct 2020 13:04:45
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 13:04:36
User entered empty; reason for change Data Entry Error	Matthew Muniz (b) (4)	15 Oct 2020 13:04:36
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:07:08

US3352299

Folder: **Unscheduled 01 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **26 Nov 2020 11:01:01**

[Physical Exam](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:07:08

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 11:01:01

[Vital Signs](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Matthew Muniz (b) (4)	15 Oct 2020 13:04:36
User entered '1'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:07:08

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 11:01:01

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:07:08

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 11:01:01

[Pregnancy Test](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:07:08

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Were vital signs assessed?

Audit	User	Time (GMT)
User closed query 'Per CDM: if confirmed that form was added in error, then please consider deleting data and inactivating the page or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:04:16
Query 'Per CDM: if confirmed that form was added in error, then please consider deleting data and inactivating the page or comment accordingly. ' answered with 'not able to inactivate the pages ' (Site from DM).	Matthew Muniz (b) (4) (b) (4)	16 Oct 2020 20:13:58
User opened query 'Per CDM: if confirmed that form was added in error, then please consider deleting data and inactivating the page or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 18:44:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 18:43:53
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	Matthew Muniz (b) (4) (b) (4)	15 Oct 2020 13:04:25
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 13:04:09
User entered empty; reason for change Data Entry Error	Matthew Muniz (b) (4) (b) (4)	15 Oct 2020 13:04:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Matthew Muniz (b) (4)	15 Oct 2020 13:04:09
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 09:08:48
Query 'Data is required. Please provide.' answered with 'TIME WAS NOT RECORDED' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 20:56:14
User opened query 'Data is required. Please provide.' System (Site from System).		01 Sep 2020 18:07:55
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Matthew Muniz (b) (4)	15 Oct 2020 13:04:09
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	15 Oct 2020 13:04:09
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	15 Oct 2020 13:04:09
User entered empty; reason for change Data Entry Error	Matthew Muniz (b) (4) (b) (4)	15 Oct 2020 13:04:09
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Sep 2020 18:07:55
User entered '44'	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 13:04:09
User entered 'bpm'	System	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Matthew Muniz (b) (4)	15 Oct 2020 13:04:09
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 13:04:09
User entered 'breaths/min'	System	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Matthew Muniz (b) (4)	15 Oct 2020 13:04:09
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 13:04:09
User entered 'mmHg'	System	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Matthew Muniz (b) (4)	15 Oct 2020 13:04:09
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 18:07:55

US3352299

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 13:04:09
User entered 'mmHg'	System	01 Sep 2020 18:07:55

US3352299

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:20:28

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:18
User entered 'USA-US066-2020-mRNA-1273-P301000005'	System	13 Nov 2020 13:23:15
User entered 'New'	(b) (4), (b) (6)	13 Nov 2020 13:23:15

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash vesicular, LLT: Vesicular rash - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:10:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:10:59
Data point term sent to Coder	System	24 Nov 2020 18:40:45
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event if biopsy or other testing/exam provides a definitive diagnosis.' answered with 'AE TERM HAS BEEN UPDATED BASED OFF OF MEDICAL RECORDS.' (Site from Safety).	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:40:24
Coding entries removed.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:39:51
User entered 'DISSEMINATED VESICULAR RASH ALL OVER BODY' reason for change: New Information	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:39:51
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event if biopsy or other testing/exam provides a definitive diagnosis.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:44:06
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral skin infection, LLT: Viral skin infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 15:48:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 15:48:31
Data point term sent to Coder	System	12 Nov 2020 15:47:26
User entered 'VIRAL SKIN CONDITION'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '08 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:39:51
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'DATE HAS BEEN UPDATED.' (Site from Safety).	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:40:41
User entered '13 Nov 2020' reason for change: New Information	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:39:51
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:43:07
User entered empty.	Rosaidaliz Carreira (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Kindly update the hospital discharge date when data is available. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:12:09
Query 'Per CDM: Kindly update the hospital discharge date when data is available. Thank you.' answered with 'DATE HAS BEEN ENTERED.' (Site from DM).	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 16:08:45
User opened query 'Per CDM: Kindly update the hospital discharge date when data is available. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 10:21:46
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 10:20:40
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Data pending. Will be updated once site has further information from the subject.' (Site from System).	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:49:49
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Nov 2020 15:46:30
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020' reason for change: New Information	Rosaidaliz Carreira (b) (4)	17 Nov 2020 16:08:31
User entered empty.	Rosaidaliz Carreira (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' answered with 'DATA UPDATED AS PER QUERY REQUEST.' (Site from Safety).	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:41:00
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4)	24 Nov 2020 18:39:51
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:42:49
User entered 'None (NONE)'	Rosaidaliz Carreira (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

None

Audit	User	Time (GMT)
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'DATA UPDATED.' (Site from Safety).	Rosaidaliz Carreira (b) (4)	(b) (4) 24 Nov 2020 18:41:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Rosaidaliz Carreira (b) (4)	(b) (4) 24 Nov 2020 18:39:51
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:43:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Rosaidaliz Carreira (b) (4)	(b) (4) 12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'MEDICATIONS HAVE BEEN ADDED TO COM MEDICATION FORM.' (Site from Safety).	Rosaidaliz Carreira (b) (4)	(b) (4) 24 Nov 2020 19:37:19
Query 'PV Query: Please provide any relevant laboratory and diagnostic test, with biopsy results, used to diagnose or monitor the viral disease. Please include units and reference ranges if applicable.' answered with 'SIGNIFICANT LAB RESULTS CONSIST OF ALT OF 138 U/L. BILIRUBIN DIRECT 0.4 MG/DL. CRP OF 122.0 MG/L. AST 102 U/L. SARS-COV-2 IgG NEGATIVE. SKIN BIOPSY, SKIN INTERPRETATION: NEGATIVE DIRECT IMMUNOFLOURESCENCE STUDY. IgG: NEGATIVE FOR CLINICALLY RELEVANT DEPOSITION. IgA: NEGATIVE FOR CLINICALLY RELEVANT DEPOSITION. IgM: NEGATIVE FOR CLINICALLY RELEVANT DEPOSITION. C3: NEGATIVE FOR CLINICALLY RELEVANT DEPOSITION. FIBRINOGEN: NEGATIVE FOR CLINICALLY RELEVANT DEPOSITION. PUNCH BIOPSY DIRECT IMMUNOFLOURESCENCE STUDIES ARE NEGATIVE FOR ANTIBODY DEPOSITION.' (Site from Safety).	Rosaidaliz Carreira (b) (4)	(b) (4) 24 Nov 2020 19:32:45
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 'SARS-CoV-2 TEST DONE ON 11NOV2020 WITH A NEGATIVE RESULT.' (Site from Safety).	Rosaidaliz Carreira (b) (4)	(b) (4) 24 Nov 2020 18:39:28

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:43:40
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test, with biopsy results, used to diagnose or monitor the viral disease. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:43:16
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)	20 Nov 2020 19:42:56
User entered 'Subject started with blisters all over his body more prominent to his mouth. He went to family doctor yesterday and was recommended to go to the hospital in view of his clinical presentation. Subject's wife reported he was admitted in the hospital yesterday 11NOV2020 at 1030 am. Had a skin biopsy done in which results are pending. She mentioned he was given a steroid antiviral and pain medications. Pending medical records.'	Rosaidaliz Carreira (b) (4)	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 15:46:30

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Transaminases increased, LLT: Transaminases increased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:09:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:09:58
Data point term sent to Coder	System	24 Nov 2020 18:46:00
User entered 'ELEVATED TRANSAMINASE LEVEL'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

Death

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:45:55
	(b) (4)	

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

None

Audit	User	Time (GMT)
User entered 'I'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Narrative](#)

Audit	User	Time (GMT)
User entered 'DATA OBTAINED FROM SUBJECTS MEDICAL RECORDS WHICH HAVE BEEN REDACTED AND SUBMITTED TO SAFETY.'	Rosaidaliz Carreira (b) (4) (b) (4)	(b) (4) 24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 18:45:55

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Skin eruption - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:31:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:31:04
Data point term sent to Coder	System	24 Nov 2020 18:49:07
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:48:25
	(b) (4)	

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered 'I'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:48:25
	(b) (4)	

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

None

Audit	User	Time (GMT)
User entered 'I'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Narrative](#)

Audit	User	Time (GMT)
User entered 'DATA OBTAINED FROM SUBJECTS MEDICAL RECORDS WHICH HAVE BEEN REDACTED AND SUBMITTED TO SAFETY.'	Rosaidaliz Carreira (b) (4) (b) (4)	(b) (4) 24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 18:48:25

US3352299

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 18:48:25

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:01:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:09:35

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:11:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:11:46
Data point term sent to Coder	System	01 Sep 2020 18:10:50
User entered 'SYNTHROID'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'HYPOTHYROIDISM'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '200'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:58:36
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'data updated' (Site from DM).	Matthew Muniz (b) (4)	29 Oct 2020 18:03:53
User entered 'ug (ug)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	29 Oct 2020 18:03:33
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 07:37:33
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:10:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: BETAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:02:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:02:59
Data point term sent to Coder	System	24 Nov 2020 18:53:17
User entered 'BETHAMETHASONE 0.05%'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'DISSEMINATED VESICULAR RASH'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'APPLICATION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:52:37
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Topical (TOPICAL)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:52:37
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:52:37
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:52:37
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 18:52:37

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:30
Data point term sent to Coder	System	24 Nov 2020 19:50:43
User entered 'PREDISONE'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'DISSEMINATED VESICULAR RASH'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 19:49:53
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 21:01:00
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	24 Nov 2020 21:01:00
User entered 'once daily (QD)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	24 Nov 2020 21:01:00
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 19:49:53
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 19:49:53
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:01:00
User entered empty.	System	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:01:00
User entered empty.	System	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 21:01:00
User entered empty.	System	24 Nov 2020 19:49:53

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 19:53:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 19:53:07
Data point term sent to Coder	System	24 Nov 2020 19:51:44
User entered 'VALTREX'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'DISSEMINATED VESICULAR RASH'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'g (g)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 19:51:04
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 19:51:04
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 19:51:04
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 19:51:04

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 23:52:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 23:52:11
Data point term sent to Coder	System	24 Nov 2020 21:00:32
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	24 Nov 2020 21:00:21
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'Data updated' (Site from System).	Rosaidaliz Carreira (b) (4)	24 Nov 2020 21:00:21
User entered 'CLARITIN (Loratadine)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	24 Nov 2020 21:00:09
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	24 Nov 2020 20:23:55
Data point term sent to Coder	System	24 Nov 2020 20:14:20
User entered 'CLARITIN'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:14:16
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'RASK SKIN ERUPTION ALL OVER BODY'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:14:16
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:14:16
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:14:16
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:14:16
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:14:16
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 20:14:16

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:25:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:25:26
Data point term sent to Coder	System	24 Nov 2020 20:23:40
User entered 'DILAUDID'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:23:18
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'RASH SKIN ERUPTION ALL OVER BODY'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:23:18
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'FOUR TIMES A DAY AS NEEDED'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:23:18
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered 'INTRAVENOUS PUSH'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:23:18
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:23:18
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:23:18
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:23:18

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: OTHER AGENTS FOR LOCAL ORAL TREATMENT, PRODUCT: ALUMINIUM HYDROXIDE;DIPHENHYDRAMINE;LIDOCAINE;MAGNESIUM HYDROXIDE;SIMETICONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 04:44:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 04:44:55
Data point term sent to Coder	System	24 Nov 2020 20:26:43
User entered 'ALUMINUM HYDROXIDE/ DIPHENHYDRAMINE/ LIDOCAINE/ MAGNESIUM HYDROXIDE/ SIMETHICORE TOPICAL'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:25:44
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'RASH SKIN ALL OVER BODY'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:25:44
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:25:44
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:25:44
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:25:44
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'EVERY THREE HOURS'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Topical (TOPICAL)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:25:44
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:25:44
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:25:44

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Name of Medication](#)

Audit	User	Time (GMT)
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:37:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:37:05
Data point term sent to Coder	System	24 Nov 2020 20:27:45
User entered 'PEPCID'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'GASTRIC PROPHYLAXIS'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:27:06
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20 / 2'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'MG / ML'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:27:06
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:27:06
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:27:06
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:27:06
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 20:27:06

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:47:29
Data point term sent to Coder	System	24 Nov 2020 20:28:45
User entered 'PREDNISONE'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:28:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:28:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:28:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:28:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:28:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:28:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:28:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:28:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:28:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 20:28:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:49:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:49:04
Data point term sent to Coder	System	24 Nov 2020 20:32:51
User entered 'HYCHROMORPHONE'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:32:49
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:32:49
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:32:49
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:32:49
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:32:49

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:48:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:48:01
Data point term sent to Coder	System	24 Nov 2020 20:33:52
User entered 'ONDANSETRON'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:33:38
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '4'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:33:38
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:33:38
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:33:38
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:33:38
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:33:38
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:33:38
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:33:38

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 02:47:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 02:47:29
Data point term sent to Coder	System	24 Nov 2020 20:34:54
User entered 'PREDNISONE'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:34:33
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:34:33
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '30'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:34:33
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:34:33
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 21:01:19
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	24 Nov 2020 21:01:19
User entered 'once daily (QD)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	24 Nov 2020 21:01:19
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 20:34:33
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:34:33
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:01:19
User entered empty.	System	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:01:19
User entered empty.	System	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 21:01:19
User entered empty.	System	24 Nov 2020 20:34:33

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 02:47:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 02:47:30
Data point term sent to Coder	System	24 Nov 2020 20:35:55
User entered 'PREDNISONE'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:35:54
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 21:01:32
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	24 Nov 2020 21:01:32
User entered 'once daily (QD)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	24 Nov 2020 21:01:32
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 20:35:54
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:01:32
User entered empty.	System	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:01:32
User entered empty.	System	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 21:01:32
User entered empty.	System	24 Nov 2020 20:35:54

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 02:47:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 02:47:30
Data point term sent to Coder	System	24 Nov 2020 20:37:56
User entered 'PREDNISONE'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:37:22
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:37:22
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:37:22
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:37:22
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:37:22
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:37:22
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:37:22
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:37:22
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:37:22
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 20:37:22

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:38:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:38:09
Data point term sent to Coder	System	24 Nov 2020 20:42:00
User entered 'SODIUM CHLORIDE 0.9%'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:41:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:41:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:41:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 21:02:01
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	24 Nov 2020 21:02:01
User entered 'once daily (QD)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	24 Nov 2020 21:02:01
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	24 Nov 2020 21:01:54
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:41:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:41:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:41:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		24 Nov 2020 21:01:54
User entered '12 Nov 2020' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	24 Nov 2020 21:01:54
User opened query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).	(b) (4)	24 Nov 2020 20:41:21
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:41:21
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:02:01
User entered empty.	System	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:02:01
User entered empty.	System	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 21:02:01
User entered empty.	System	24 Nov 2020 20:41:21

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 23:01:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 23:01:11
Data point term sent to Coder	System	24 Nov 2020 20:47:13
User entered 'TRIAMCINOLONE 0.01%'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:46:58
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:46:58
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'APPLICATION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:46:58
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Topical (TOPICAL)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:46:58
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 20:46:58

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4)	24 Nov 2020 20:49:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:49:06
Data point term sent to Coder	System	24 Nov 2020 20:48:14
User entered 'ACETAMINOPHEN'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:48:00
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'RASH SKIN ERUPTION'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:48:00
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:48:00
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 20:48:00
	(b) (4)	

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:48:00

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:01:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 17:15:02

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:01:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:04:35

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:01:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'PUNCH BIOPSY'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:04:35

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:04:35
	(b) (4)	

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:01:01

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:04:35
	(b) (4)	

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:01:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:07:09

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:01:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'SKIN BIOPSY RIGHT ARM'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:07:09

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:07:09
	(b) (4)	

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:01:01

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:07:09

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:01:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:33:39

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:01:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'SKIN BIOPSY'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:33:39

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:01:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Rosaidaliz Carreira (b) (4) (b) (4)	24 Nov 2020 18:33:39

US3352299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:01:01

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	24 Nov 2020 18:33:39
	(b) (4)	

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'USA-US066-2020-MRNA-1273-P301000005'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Howard'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'schwartz'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '7265 SHeridan Street SUite 210'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Pembroke Pines'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'FL'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '33024'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'US'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Nov 2020 14:33:51
User entered '1'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'USA-US066-2020-MRNA-1273-P301000005'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Howard'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'schwartz'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '7265 SHeridan Street SUite 210'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Pembroke Pines'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'FL'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '33024'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'US'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Nov 2020 14:33:51
User entered '1'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:01:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '13/Nov/2020 08:23'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:01:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'USA-US066-2020-MRNA-1273-P301000005'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Yes (Y)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'No (N)'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Howard'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'schwartz'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '7265 SHeridan Street SUite 210'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'Pembroke Pines'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered 'FL'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:23:29
User entered '33024'	System	13 Nov 2020 13:23:15

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:32:08
User entered 'US'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Nov 2020 14:33:51
User entered '1'	System	13 Nov 2020 13:23:35

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:01:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '18/Nov/2020 14:33'	System	18 Nov 2020 14:33:51

US3352299

Folder: SAE USA-US066-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:01:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 14:33:51