

US3732304 (Prod: eStudySite - La Mesa - PPDS)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:13:28

All time stamps listed in this document are displayed in GMT

US3732304

Form: Participant Creation

Generated On: 26 Nov 2020 11:13:28

[Participant ID](#)

US3732304

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	55
Age Units	YEARS
Age (Derived)	56
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:28

Date of Informed Consent (<i>dd MMM yyyy</i>)	09 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:13:28

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:13:28

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:28

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1965
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1965
Start Year (derived)	1965
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:28

Condition	ALLERGY TO PET DANDER
Start date (dd MMM yyyy)	UN UNK 1978
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1978
Start Year (derived)	1978
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:28

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:28

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:28

Condition	MYOPIA BILATERAL
Start date (dd MMM yyyy)	UN UNK 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:28

Condition	FREQUENT URINARY TRACT INFECTIONS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:28

Condition	CHRONIC BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:28

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:28

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:28

Condition	PERI MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:28

Condition	CYSTOCELE SURGERY
Start date (dd MMM yyyy)	16 NOV 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	16 NOV 2013
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2013
Start Year (derived)	2013
Stop Month and Year (derived)	NOV 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:28

Condition	CYSTOCELE SURGERY
Start date (dd MMM yyyy)	17 AUG 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	17 AUG 2015
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2015
Start Year (derived)	2015
Stop Month and Year (derived)	AUG 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:28

Condition	RIGHT TRIGGER FINGER RELEASE
Start date (dd MMM yyyy)	12 JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	12 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:28

Condition	CHRONIC NECK PAIN
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:28

Condition	CYSTOCELE
Start date (dd MMM yyyy)	16 NOV 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	16 NOV 2013
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2013
Start Year (derived)	2013
Stop Month and Year (derived)	NOV 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:28

Condition	CYSTOCELE
Start date (dd MMM yyyy)	17 AUG 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	17 AUG 2015
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2015
Start Year (derived)	2015
Stop Month and Year (derived)	AUG 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:28

Condition	RIGHT CARPAL TUNNEL RELEASE
Start date (dd MMM yyyy)	12 JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	12 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

US3732304

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:28

Condition	RIGHT TRIGGER FINGER SURGERY
Start date (dd MMM yyyy)	12 JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	12 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:28

Condition	RIGHT CARPAL TUNNEL SURGERY
Start date (dd MMM yyyy)	12 JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	12 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	09 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:48 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 14:48
Height (<i>xxx.x</i>)	167.0 cm
Weight (<i>xxx.x</i>)	79.0 kg
BMI (<i>xxx.x</i>)	28.32658 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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 11:13:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:28

Date of assessment (*dd MMM yyyy*) 09 SEP 2020

Is the participant of childbearing potential? Yes ☒ No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	09 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:28

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 112827

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 11:13:28

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 11:13:28

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	09 SEP 2020
Time of assessment (00:00-23:59)	14:48 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 14:48
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 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 11:13:28

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	09 SEP 2020
Time of assessment (00:00-23:59)	16:37 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 16:37
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:28

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: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed _____ Urine ☐

Serum ☐

Result _____ Positive ☐

Negative ☐

Was FSH sample collected? Yes ☐

No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	09 SEP 2020
What was the treatment time? (00:00-23:59)	16:07 (24 HR)
Treatment Date and Time (derived)	09 SEP 2020 16:07
Which arm was used to give treatment?	Left Arm ☐
	Right Arm ☒
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:28

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

09 SEP 2020

Collection time (*00:00-23:59*)

15:27 (24 HR)

Collection date and time (derived)

09 SEP 2020 15:27

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:13:28

Collection date (<i>dd MMM yyyy</i>)			09 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	15:23	09 SEP 2020 15:23
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

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 11:13:28

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

98.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp 09 SEP 2020 16:43

PC Open Date & Time 09 SEP 2020 16:27

PC Close Date & Time 09 SEP 2020 18:57

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 09 SEP 2020 19:52

PC Close Date & Time 10 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 19:04

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

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

98.9 °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

11 SEP 2020 22:00

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

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	98.1 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	12 SEP 2020 22:30
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 21:45

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 18:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 19:05

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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

09 SEP 2020 16:43

PC Open Date & Time

09 SEP 2020 16:27

PC Close Date & Time

09 SEP 2020 18:57

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

09 SEP 2020 19:52

PC Close Date & Time

10 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 19:05

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 21:43

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 22:30

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 21:46

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 18:02

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 19:05

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 16:44
PC Open Date & Time	09 SEP 2020 16:27
PC Close Date & Time	09 SEP 2020 18:57

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 19:52

PC Close Date & Time

10 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

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 ☒

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

Yes ☐	
PC Time stamp	10 SEP 2020 19:05
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

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 ☒

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

Yes ☐	
PC Time stamp	11 SEP 2020 21:44
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

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 ☒

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

Yes ☐	
PC Time stamp	12 SEP 2020 22:31
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

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 ☒

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

Yes ☐	
PC Time stamp	13 SEP 2020 21:46
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

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 ☒

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

Yes ☐	
PC Time stamp	14 SEP 2020 18:03
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

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 ☒

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

Yes ☐	
PC Time stamp	15 SEP 2020 19:06
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 17 SEP 2020 10:32

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	17 SEP 2020 10:33
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3732304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732304

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732304

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732304

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 13:25
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	14:56 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 14:56
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3732304

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 OCT 2020

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

US3732304

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	07 OCT 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	07 OCT 2020
What was the treatment time? (00:00-23:59)	14:26 (24 HR)
Treatment Date and Time (derived)	07 OCT 2020 14:26
Which arm was used to give treatment?	Left Arm ☐
	Right Arm ☒
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3732304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:28

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	07 OCT 2020
Collection time (<i>00:00-23:59</i>)	14:20 (24 HR)
Collection date and time (derived)	07 OCT 2020 14:20

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:13:28

Collection date (<i>dd MMM yyyy</i>)			07 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:58	07 OCT 2020 13:58
Nasopharyngeal Swab 2	No		

US3732304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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

98.7 °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

07 OCT 2020 15:00

PC Open Date & Time

07 OCT 2020 14:46

PC Close Date & Time

07 OCT 2020 17:16

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °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	08 OCT 2020 11:01
PC Open Date & Time	07 OCT 2020 18:11
PC Close Date & Time	08 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 19:31

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp 09 OCT 2020 19:46

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

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

99.2 °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

10 OCT 2020 19:03

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

12 OCT 2020 01:42

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:28

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

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

98.6 °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

13 OCT 2020 13:18

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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

07 OCT 2020 15:01

PC Open Date & Time

07 OCT 2020 14:46

PC Close Date & Time

07 OCT 2020 17:16

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 11:01

PC Open Date & Time

07 OCT 2020 18:11

PC Close Date & Time

08 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

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

08 OCT 2020 19:32

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 00:00

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

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

10 OCT 2020 19:03

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 OCT 2020 01:42

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:28

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

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

13 OCT 2020 13:18

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 15:01
PC Open Date & Time	07 OCT 2020 14:46
PC Close Date & Time	07 OCT 2020 17:16

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 11:02
PC Open Date & Time	07 OCT 2020 18:11
PC Close Date & Time	08 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

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 ☒

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

Yes ☐	
PC Time stamp	08 OCT 2020 19:32
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

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 ☒

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

Yes ☐	
PC Time stamp	10 OCT 2020 00:00
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

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 ☒

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

Yes ☐	
PC Time stamp	10 OCT 2020 19:03
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

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 ☒

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

Yes ☐	
PC Time stamp	12 OCT 2020 01:43
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

		Yes ☐
PC Time stamp		
PC Open Date & Time		12 OCT 2020 12:00
PC Close Date & Time		13 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

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 ☒

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

Yes ☐	
PC Time stamp	13 OCT 2020 13:19
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 14 OCT 2020 23:07

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(10)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 10

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 ☐

PC Time Stamp

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	14 OCT 2020 23:08
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 10

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3732304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732304

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732304

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732304

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3732304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

Were vital signs assessed?	Yes ☐
	No ☐
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 ☐
	Axillary ☐
	Other ☐
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)	

US3732304

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:28

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.

US3732304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:28

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00-23:59</i>)	
Collection date and time (derived)	

US3732304

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

11 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 103

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

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 138

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

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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05 FEB 2021 00:01

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09 FEB 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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12 FEB 2021 00:01

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16 FEB 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 166

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

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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19 FEB 2021 00:01

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23 FEB 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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02 MAR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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09 MAR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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12 MAR 2021 00:01

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16 MAR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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09 APR 2021 00:01

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13 APR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 243

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

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

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

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

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

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

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 334

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

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

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

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

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

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

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 432

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

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

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

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

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

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

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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28 JAN 2022 00:01

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01 FEB 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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04 FEB 2022 00:01

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08 FEB 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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11 FEB 2022 00:01

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15 FEB 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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22 FEB 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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Date and time of submission

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01 MAR 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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Date and time of submission

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

Date and time of submission

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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08 APR 2022 00:01

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12 APR 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

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19 APR 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

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Date and time of submission

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22 APR 2022 00:01

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26 APR 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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29 APR 2022 00:01

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03 MAY 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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07 JUN 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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14 JUN 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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28 JUN 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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12 JUL 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

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26 JUL 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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05 AUG 2022 00:01

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09 AUG 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 705

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

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

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

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

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

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

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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23 AUG 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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06 SEP 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 733

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

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

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

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

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

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

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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11 OCT 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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14 OCT 2022 00:01

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18 OCT 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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25 OCT 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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28 OCT 2022 00:01

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01 NOV 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

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08 NOV 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

DAY 796

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

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

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

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

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

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

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 ☐

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

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

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3732304

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:13:28

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3732304

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:13:28

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3732304

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:13:28

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

AEID	
Adverse event	PAIN AT INJECTION SITE
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☒ No ☐
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	08 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	18 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

AEID	USA-US102-2020-MRNA-1273-P30 1000004
Adverse event	BILATERAL PULMONARY EMBOLISM
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☒ No ☐
Start date (dd MMM yyyy)	29 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

SUBJECT CALLED SITE TO
REPORT ABOVE AE AND
HOSPITALIZATION FROM
10/29/20 - ONGOING. SUBJECT IS
ADMITTED AT UCSD, MEDICAL
RECORDS WILL BE REQUESTED
UPON SUBJECT'S RETURN TO
SITE. SUBJECT DENIED ANY
RECENT TRAVEL, SMOKER OR
ORAL BC. SUBJECT REPORTED
TWO NEGATIVE TESTS FOR
COVID, PERFORMED IN
HOSPITAL. PER SUBJECT,
UNKNOWN CAUSE AT THIS
TIME. SUBJECT STATED IT WAS
99% OCCLUDED.

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)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:13:28

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

Yes ☒

No ☐

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

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	ZYRTEC
Prophylaxis	Yes ☐ No ☒
Indication	PET DANDER AND ENVIRONMENTAL ALLERGIES
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		UN UNK 1978
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	ALBUTEROL
Prophylaxis	Yes ☐ No ☒
Indication	ASTHMA
Dose per administration	90
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1974
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	PANTOPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	GASTROESOPHAGEAL REFLUX DISEASE
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1998
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC BACK PAIN
Dose per administration	1200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	NORCO
Prophylaxis	Yes ☐ No ☒
Indication	POST SURGICAL PAIN
Dose per administration	10/325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	ESTRADIOL 0.01% CREAM
Prophylaxis	Yes ☐ No ☒
Indication	PERI-MENOPAUSE
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	PUMP
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☒ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☒ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	NUVA RING
Prophylaxis	Yes ☒ No ☐
Indication	PREGNANCY
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	RING
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☒ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☒
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☒
	803 ☐
	804 ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	AMITRIPTYLINE
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION / INSOMNIA
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1996
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	FLUOXETINE
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
Dose per administration	50
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	WELLBUTRIN
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
Dose per administration	450
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1996
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	MAGNESIUM
Prophylaxis	Yes ☒ No ☐
Indication	VITAMIN DEFICIENCY
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1998
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ☒ No ☐
Indication	VITAMIN DEFICIENCY
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1998
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	VITAMIN D3
Prophylaxis	Yes ☒ No ☐
Indication	VITAMIN DEFICIENCY
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1998
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	ZINC
Prophylaxis	Yes ☒ No ☐
Indication	VITAMIN DEFICIENCY
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1998
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	HEPARIN
Prophylaxis	Yes ☐ No ☒
Indication	BILATERAL PULMONARY EMBOLISM
Dose per administration	50
Dose unit	mg ☐ ug ☐ mL ☒ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	DRIP Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☒
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		03 NOV 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

Name of Medication	ELOQUIS
Prophylaxis	Yes ☐ No ☒
Indication	SAE- BILATERAL PULMONARY EMBOLISM
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3732304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:13:28

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3732304

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:13:28

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

US3732304

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:13:28

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 ☐

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

SAEID	USA-US102-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:13:28

SAEID	USA-US102-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	04/NOV/2020 16:38
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

US3732304 (Prod: eStudySite - La Mesa - PPDS)

US3732304

Form: Participant Creation

Generated On: 26 Nov 2020 11:13:28

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:29:44
User entered 'US3732304'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 21:39:21

US3732304

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:32:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:36:32

US3732304

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:32:53
User entered '09 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 21:39:22

US3732304

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:32:53
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:36:32

US3732304

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	10 Sep 2020 17:36:32

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered (b) (6) 1964'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 21:39:23

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '55'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	10 Sep 2020 17:42:13

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '56'	System	09 Sep 2020 23:12:52

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

Sex

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered 'Female (F)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

White

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '1'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '1'	Lauren Arnett (b) (4)	10 Sep 2020 17:42:13
	(b) (4)	

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

Unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 17:42:13
	(b) (4)	

US3732304

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:28

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

US3732304

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:28

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered '09 Sep 2020'	Lauren Arnett (b) (4)	09 Sep 2020 23:12:52
	(b) (4)	

US3732304

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	09 Sep 2020 23:12:52

US3732304

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2020'	System	09 Sep 2020 23:12:52

US3732304

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:28

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered 'Amendment 3 (3)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:12:52

US3732304

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:12:52

US3732304

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered empty.	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:12:52

US3732304

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:28

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered empty.	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:12:52

US3732304

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:28

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:12:52

US3732304

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:28

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 21:39:22

US3732304

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:28

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 23:12:58

US3732304

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:44
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:12:58

US3732304

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:13:28

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:33:51
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:34

US3732304

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:43:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	10 Sep 2020 17:43:45
Data point term sent to Coder	System	10 Sep 2020 17:43:16
User entered 'environmental allergies'	Lauren Arnett (b) (4)	10 Sep 2020 17:42:54
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1965'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:54

US3732304

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:54

US3732304

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:54

US3732304

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:54

US3732304

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:54

US3732304

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jan 1965'	System	10 Sep 2020 17:42:54

US3732304

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '1965'	System	10 Sep 2020 17:42:54

US3732304

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:42:54

US3732304

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:42:54

US3732304

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to animal, LLT: Allergy to animal dander - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:43:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	10 Sep 2020 17:43:45
Data point term sent to Coder	System	10 Sep 2020 17:43:17
User entered 'allergy to pet dander'	Lauren Arnett (b) (4)	10 Sep 2020 17:43:06
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1978'	Lauren Arnett (b) (4)	10 Sep 2020 17:43:06
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:06

US3732304

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:06

US3732304

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:06

US3732304

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 17:43:06
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jan 1978'	System	10 Sep 2020 17:43:06

US3732304

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '1978'	System	10 Sep 2020 17:43:06

US3732304

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:43:06

US3732304

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:43:06

US3732304

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:45:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	10 Sep 2020 17:45:46
Data point term sent to Coder	System	10 Sep 2020 17:44:18
User entered 'asthma'	Lauren Arnett (b) (4)	10 Sep 2020 17:43:24
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1974'	Lauren Arnett (b) (4)	10 Sep 2020 17:43:24
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:24

US3732304

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:24

US3732304

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:24

US3732304

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 17:43:24
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jan 1974'	System	10 Sep 2020 17:43:24

US3732304

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '1974'	System	10 Sep 2020 17:43:24

US3732304

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:43:24

US3732304

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:43:24

US3732304

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastrooesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:46:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:46:49
Data point term sent to Coder	System	10 Sep 2020 17:45:23
User entered 'gastroesophageal reflux disease'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:37

US3732304

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1998'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:37

US3732304

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:37

US3732304

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:37

US3732304

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:37

US3732304

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 17:44:37
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	10 Sep 2020 17:44:37

US3732304

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '1998'	System	10 Sep 2020 17:44:37

US3732304

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:44:37

US3732304

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:44:37

US3732304

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:46:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:46:24
Data point term sent to Coder	System	19 Oct 2020 16:45:50
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:45:30
User entered 'MYOPIA bilateral' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:45:30
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:46:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:46:49
Data point term sent to Coder	System	10 Sep 2020 17:45:23
User entered 'myopia'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:47

US3732304

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1974'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:47

US3732304

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:47

US3732304

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:47

US3732304

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:47

US3732304

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:47

US3732304

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jan 1974'	System	10 Sep 2020 17:44:47

US3732304

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '1974'	System	10 Sep 2020 17:44:47

US3732304

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:44:47

US3732304

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:44:47

US3732304

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:47:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:47:38
Data point term sent to Coder	System	10 Sep 2020 17:46:27
User entered 'frequent urinary tract infections'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:28

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 2015'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:28

US3732304

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 17:45:28
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:28

US3732304

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:28

US3732304

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 17:45:28
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	10 Sep 2020 17:45:28

US3732304

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2015'	System	10 Sep 2020 17:45:28

US3732304

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:45:28

US3732304

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:45:28

US3732304

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:53:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:53:49
Data point term sent to Coder	System	21 Sep 2020 16:52:55
User entered 'CHRONIC BACK PAIN' reason for change: New Information	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:52:21
Data point term sent to Coder	System	10 Sep 2020 17:46:27
User entered 'chronic neck and back pain'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:43

US3732304

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:43

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:43

US3732304

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:43

US3732304

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:43

US3732304

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 17:45:43
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	10 Sep 2020 17:45:43

US3732304

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2010'	System	10 Sep 2020 17:45:43

US3732304

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:45:43

US3732304

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:45:43

US3732304

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:47:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	10 Sep 2020 17:47:37
Data point term sent to Coder	System	10 Sep 2020 17:46:28
User entered 'insomnia'	Lauren Arnett (b) (4)	10 Sep 2020 17:45:53
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1996'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:53

US3732304

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:53

US3732304

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	10 Sep 2020 17:45:53
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:53

US3732304

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 17:45:53
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jan 1996'	System	10 Sep 2020 17:45:53

US3732304

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '1996'	System	10 Sep 2020 17:45:53

US3732304

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:45:53

US3732304

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:45:53

US3732304

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:47:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	10 Sep 2020 17:47:37
Data point term sent to Coder	System	10 Sep 2020 17:46:29
User entered 'depression'	Lauren Arnett (b) (4)	10 Sep 2020 17:46:03
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1996'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:46:03

US3732304

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 17:46:03
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:46:03

US3732304

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:46:03

US3732304

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:46:03

US3732304

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jan 1996'	System	10 Sep 2020 17:46:03

US3732304

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '1996'	System	10 Sep 2020 17:46:03

US3732304

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:46:03

US3732304

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:46:03

US3732304

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Perimenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 09:41:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 09:41:24
Data point term sent to Coder	System	10 Sep 2020 17:50:37
User entered 'peri menopause'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:50:37

US3732304

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 2017'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:50:37

US3732304

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 17:50:37
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:50:37

US3732304

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:50:37

US3732304

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:50:37

US3732304

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	10 Sep 2020 17:50:37

US3732304

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2017'	System	10 Sep 2020 17:50:37

US3732304

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:50:37

US3732304

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:50:37

US3732304

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Bladder therapeutic procedures, PT: Cystocele repair, LLT: Cystocele repair - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 05:10:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 05:10:49
Data point term sent to Coder	System	10 Sep 2020 17:51:39
User entered 'cystocele surgery'	Lauren Arnett (b) (4)	10 Sep 2020 17:51:24
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '16 Nov 2013'	Lauren Arnett (b) (4)	10 Sep 2020 17:51:24
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:24

US3732304

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 17:51:24
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '16 Nov 2013'	Lauren Arnett (b) (4)	10 Sep 2020 17:51:24
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 17:51:24
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Nov 2013'	System	10 Sep 2020 17:51:24

US3732304

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2013'	System	10 Sep 2020 17:51:24

US3732304

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Nov 2013'	System	10 Sep 2020 17:51:24

US3732304

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2013'	System	10 Sep 2020 17:51:24

US3732304

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Bladder therapeutic procedures, PT: Cystocele repair, LLT: Cystocele repair - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 05:10:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 05:10:49
Data point term sent to Coder	System	10 Sep 2020 17:52:41
User entered 'cystocele surgery'	Lauren Arnett (b) (4)	10 Sep 2020 17:51:49
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '17 Aug 2015'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:49

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:49

US3732304

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 17:51:49
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '17 Aug 2015'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:49

US3732304

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:49

US3732304

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Aug 2015'	System	10 Sep 2020 17:51:49

US3732304

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2015'	System	10 Sep 2020 17:51:49

US3732304

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Aug 2015'	System	10 Sep 2020 17:51:49

US3732304

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2015'	System	10 Sep 2020 17:51:49

US3732304

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:28

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Tendon therapeutic procedures, PT: Tendon sheath incision, LLT: Trigger finger release - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 13:06:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 13:06:52
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
Data point term sent to Coder	System	03 Nov 2020 00:29:00
User closed query 'Per CDM Coding: Multiple medical concepts are reported. Please split into separate records, e.g. one of RIGHT TRIGGER FINGER RELEASE and one of CARPAL TUNNEL RELEASE etc.' (Site from System).	System	03 Nov 2020 00:28:18
Query 'Per CDM Coding: Multiple medical concepts are reported. Please split into separate records, e.g. one of RIGHT TRIGGER FINGER RELEASE and one of CARPAL TUNNEL RELEASE etc.' answered with 'updated' (Site from System).	Lauren Arnett (b) (4) (b) (4)	03 Nov 2020 00:28:18
User entered 'RIGHT TRIGGER FINGER RELEASE' reason for change: New Information	Lauren Arnett (b) (4) (b) (4)	03 Nov 2020 00:28:11
User opened query 'Per CDM Coding: Multiple medical concepts are reported. Please split into separate records, e.g. one of RIGHT TRIGGER FINGER RELEASE and one of CARPAL TUNNEL RELEASE etc.' (Site from System).	Coder Import (b) (4) (b) (4)	20 Oct 2020 12:22:29
Data point term sent to Coder	System	21 Sep 2020 16:52:56
Coding entries removed.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:52:54
User entered 'RIGHT trigger finger - carpal tunnel release' reason for change: New Information	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:52:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Limb operation, LLT: Hand operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:53:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:53:47
Data point term sent to Coder	System	10 Sep 2020 17:52:42
User entered 'right hand surgery'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:52:06

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '12 Jun 2020'	Lauren Arnett (b) (4)	10 Sep 2020 17:52:06
	(b) (4)	

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:52:06

US3732304

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 17:52:06
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '12 Jun 2020'	Lauren Arnett (b) (4)	10 Sep 2020 17:52:06
	(b) (4)	

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 17:52:06
	(b) (4)	

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	10 Sep 2020 17:52:06

US3732304

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2020'	System	10 Sep 2020 17:52:06

US3732304

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	10 Sep 2020 17:52:06

US3732304

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2020'	System	10 Sep 2020 17:52:06

US3732304

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:54:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:54:52
Data point term sent to Coder	System	21 Sep 2020 16:53:57
User entered 'chronic neck pain'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:13

US3732304

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:13

US3732304

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:13

US3732304

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:13

US3732304

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:13

US3732304

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:13

US3732304

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	21 Sep 2020 16:53:13

US3732304

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2010'	System	21 Sep 2020 16:53:13

US3732304

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:53:13

US3732304

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:53:13

US3732304

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Pelvic prolapse conditions, PT: Cystocele, LLT: Cystocele - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:54:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:54:52
Data point term sent to Coder	System	21 Sep 2020 16:53:57
User entered 'cystocele'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:32

US3732304

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '16 Nov 2013'	Lauren Arnett (b) (4)	21 Sep 2020 16:53:32
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:32

US3732304

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:32

US3732304

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '16 Nov 2013'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:32

US3732304

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	21 Sep 2020 16:53:32
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Nov 2013'	System	21 Sep 2020 16:53:32

US3732304

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2013'	System	21 Sep 2020 16:53:32

US3732304

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Nov 2013'	System	21 Sep 2020 16:53:32

US3732304

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2013'	System	21 Sep 2020 16:53:32

US3732304

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Pelvic prolapse conditions, PT: Cystocele, LLT: Cystocele - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 16:54:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	21 Sep 2020 16:54:52
Data point term sent to Coder	System	21 Sep 2020 16:53:58
User entered 'cystocele'	Lauren Arnett (b) (4)	21 Sep 2020 16:53:55
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '17 Aug 2015'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:55

US3732304

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:55

US3732304

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Sep 2020 16:53:55
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '17 Aug 2015'	Lauren Arnett (b) (4)	21 Sep 2020 16:53:55
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	21 Sep 2020 16:53:55
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Aug 2015'	System	21 Sep 2020 16:53:55

US3732304

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2015'	System	21 Sep 2020 16:53:55

US3732304

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Aug 2015'	System	21 Sep 2020 16:53:55

US3732304

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2015'	System	21 Sep 2020 16:53:55

US3732304

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 00:33:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 00:33:13
Data point term sent to Coder	System	03 Nov 2020 00:32:03
User closed query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. one of RIGHT TRIGGER FINGER and one of CARPAL TUNNEL SYNDROM etc.' (Site from System).	System	03 Nov 2020 00:31:22
Query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. one of RIGHT TRIGGER FINGER and one of CARPAL TUNNEL SYNDROM etc.' answered with 'updated' (Site from System).	Lauren Arnett (b) (4) (b) (4)	03 Nov 2020 00:31:22
User entered 'RIGHT carpal tunnel release' reason for change: New Information	Lauren Arnett (b) (4) (b) (4)	03 Nov 2020 00:31:11
User opened query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. one of RIGHT TRIGGER FINGER and one of CARPAL TUNNEL SYNDROM etc.' (Site from System).	Coder Import (b) (4) (b) (4)	20 Oct 2020 12:21:29
Data point term sent to Coder	System	21 Sep 2020 16:55:01
User entered 'right trigger finger- carpal tunnel'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:54:26

US3732304

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '12 Jun 2020'	Lauren Arnett (b) (4)	21 Sep 2020 16:54:26
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	21 Sep 2020 16:54:26
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Sep 2020 16:54:26
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '12 Jun 2020'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:54:26

US3732304

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4)	21 Sep 2020 16:54:26
	(b) (4)	

US3732304

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	21 Sep 2020 16:54:26

US3732304

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Sep 2020 16:54:26

US3732304

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	21 Sep 2020 16:54:26

US3732304

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Sep 2020 16:54:26

US3732304

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Tendon therapeutic procedures, PT: Tendon sheath incision, LLT: Trigger finger release - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:06:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:06:31
Data point term sent to Coder	System	07 Nov 2020 00:12:16
User entered 'Right Trigger Finger Surgery'	(b) (4), (b) (6)	07 Nov 2020 00:11:08

US3732304

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered '12 Jun 2020'	(b) (4), (b) (6)	07 Nov 2020 00:11:08

US3732304

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 00:11:08

US3732304

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 00:11:08

US3732304

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered '12 Jun 2020'	(b) (4), (b) (6)	07 Nov 2020 00:11:08

US3732304

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 00:11:08

US3732304

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	07 Nov 2020 00:11:08

US3732304

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2020'	System	07 Nov 2020 00:11:08

US3732304

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	07 Nov 2020 00:11:08

US3732304

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2020'	System	07 Nov 2020 00:11:08

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:28

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 00:13:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 00:13:25
Data point term sent to Coder	System	07 Nov 2020 00:12:16
User entered 'Right Carpal Tunnel Surgery'	(b) (4), (b) (6)	07 Nov 2020 00:11:28

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered '12 Jun 2020'	(b) (4), (b) (6)	07 Nov 2020 00:11:28

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 00:11:28

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 00:11:28

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered '12 Jun 2020'	(b) (4), (b) (6)	07 Nov 2020 00:11:28

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 00:11:28

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	07 Nov 2020 00:11:28

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2020'	System	07 Nov 2020 00:11:28

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	07 Nov 2020 00:11:28

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '2020'	System	07 Nov 2020 00:11:28

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	10 Sep 2020 17:59:31
	(b) (4)	

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered '09 Sep 2020'	Lauren Arnett (b) (4)	10 Sep 2020 17:59:31
	(b) (4)	

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered '14:48'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '09 Sep 2020 14:48'	System	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered '167.0' cm	Lauren Arnett (b) (4)	10 Sep 2020 17:59:31
DataPoint set to visible.	(b) (4) System	09 Sep 2020 23:12:58

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered '79.0' kg	Lauren Arnett (b) (4)	10 Sep 2020 17:59:31
DataPoint set to visible.	(b) (4) System	09 Sep 2020 23:12:58

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '28.32658'	System	10 Sep 2020 17:59:31
DataPoint set to visible.	System	09 Sep 2020 23:12:58

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	10 Sep 2020 17:59:31
DataPoint set to visible.	System	09 Sep 2020 23:12:58

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

[Pulse units](#)

Audit	User	Time (GMT)
Query 'Per CDM: Units of measure (Pulse BPM, Respiratory Rate BREATHS/MIN, Systolic and Diastolic Blood Pressure MMHG) should not be recorded if value is blank or ND. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 20:59:32
User opened query 'Per CDM: Units of measure (Pulse BPM, Respiratory Rate BREATHS/MIN, Systolic and Diastolic Blood Pressure MMHG) should not be recorded if value is blank or ND. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 07:47:46
User entered 'bpm'	System	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:17
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:39

US3732304

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:17
User entered '09 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:39

US3732304

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:28

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered '09 Sep 2020'	Lauren Arnett (b) (4)	10 Sep 2020 18:01:20
	(b) (4)	

US3732304

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20

US3732304

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20

US3732304

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20

US3732304

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20

US3732304

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:28

[Date of surgery unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20

US3732304

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20

US3732304

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:28

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 18:01:20
	(b) (4)	

US3732304

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:35

US3732304

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered '09 Sep 2020'	Lauren Arnett (b) (4)	10 Sep 2020 18:01:35
	(b) (4)	

US3732304

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Test performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered 'Urine (URINE)'	Lauren Arnett (b) (4)	10 Sep 2020 18:01:35
	(b) (4)	

US3732304

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Result](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered 'Negative (NEGATIVE)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:35

US3732304

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 18:01:35
	(b) (4)	

US3732304

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Collection date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:35

US3732304

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Collection time](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:35

US3732304

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:01:35

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

[Warehouse shipping and fulfillment centers](#) and jobs (e.g., [Amazon facilities](#))

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 18:02:26
	(b) (4)	

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 18:02:26
	(b) (4)	

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered '1'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:28

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:42:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:44

US3732304

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:42:36
User entered '09 Sep 2020'	Lauren Arnett (b) (4)	10 Sep 2020 18:02:44
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:42:36
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:44

US3732304

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	10 Sep 2020 18:02:44

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered '09 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 22:24:20

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered '112827'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 22:24:20

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 22:24:20

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:03:15

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:03:15

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:03:15

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:28

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:03:15

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:28

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:03:15

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Sep 2020 16:52:01
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 05:54:08
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:54:06

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:28

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:41:56
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:51:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:51:46
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:35:46
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:28

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4)	21 Sep 2020 16:51:46
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:28

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:41:56
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:51:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:51:46
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:35:46
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:28

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4)	21 Sep 2020 16:51:46
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '09 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '14:48'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '09 Sep 2020 14:48'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '98.7' F	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '90'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '16'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '126'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '86'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:28

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:41:56
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:51:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:51:46
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:35:46
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:28

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4)	21 Sep 2020 16:51:46
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '09 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '16:37'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '09 Sep 2020 16:37'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '98.4' F	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '89'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '16'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '113'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '77'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:09

US3732304

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:01
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:09

US3732304

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:26
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:14

US3732304

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:27
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:14

US3732304

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Test performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:29
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:14

US3732304

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Result](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:30
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:14

US3732304

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 20:59:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:05:14
Query 'per CDM: please select yes or no for this field' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:25:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:25:29
User opened query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 15:34:23
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:05:14

US3732304

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Collection date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:32
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:14

US3732304

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Collection time](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:34
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:14

US3732304

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:05:14

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	09 Sep 2020 23:13:18
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered '09 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered '16:07'	Lauren Arnett (b) (4)	09 Sep 2020 23:13:18
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '09 Sep 2020 16:07'	System	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered 'Right Arm (RIGHT ARM)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered 'ONCE'	System	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:52
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:31

US3732304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:52
User entered '09 Sep 2020'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:31
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:52
User entered '15:27'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:31
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '09 Sep 2020 15:27'	System	10 Sep 2020 18:05:31

US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:13:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:01
User entered '09 Sep 2020'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:41
	(b) (4)	

US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:28

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:41

US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:01
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:41

US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:01
User entered '15:23'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:41

US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '09 Sep 2020 15:23'	System	10 Sep 2020 18:05:41

US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:28

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:41

US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:41

US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:01
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:41

US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:05:41

US3732304

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:48

US3732304

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 18:05:48

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd7b2d65d-3d50-4387-98b5-98940cbf3990'	System	09 Sep 2020 23:43:25
User entered 'Yes (Y)'	System	09 Sep 2020 23:43:25

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:09', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd7b2d65d-3d50-4387-98b5-98940cbf3990'	System	09 Sep 2020 23:43:25
User entered '98.4'	System	09 Sep 2020 23:43:25

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:14', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd7b2d65d-3d50-4387-98b5-98940cbf3990'	System	09 Sep 2020 23:43:25
User entered 'No (N)'	System	09 Sep 2020 23:43:25

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:21', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd7b2d65d-3d50-4387-98b5-98940cbf3990'	System	09 Sep 2020 23:43:25
User entered '09 Sep 2020 16:43'	System	09 Sep 2020 23:43:25

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 16:27'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 18:57'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 19:52'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 2'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:03:20', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd85ddf7c-6e80-4ab8-aae1-ef665d2db0fd'	System	11 Sep 2020 02:04:44
User entered 'Yes (Y)'	System	11 Sep 2020 02:04:44

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:28', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd85ddf7c-6e80-4ab8-aae1-ef665d2db0fd'	System	11 Sep 2020 02:04:44
User entered '99.0'	System	11 Sep 2020 02:04:44

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:31', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd85ddf7c-6e80-4ab8-aae1-ef665d2db0fd'	System	11 Sep 2020 02:04:44
User entered 'No (N)'	System	11 Sep 2020 02:04:44

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:38', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd85ddf7c-6e80-4ab8-aae1-ef665d2db0fd'	System	11 Sep 2020 02:04:44
User entered '10 Sep 2020 19:04'	System	11 Sep 2020 02:04:44

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 3'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:59:32', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '994300a2-4884-490e-81fb-5a6087d41740'	System	12 Sep 2020 05:00:43
User entered 'Yes (Y)'	System	12 Sep 2020 05:00:43

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T22:00:23', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '994300a2-4884-490e-81fb-5a6087d41740'	System	12 Sep 2020 05:00:43
User entered '98.9'	System	12 Sep 2020 05:00:43

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T22:00:34', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '994300a2-4884-490e-81fb-5a6087d41740'	System	12 Sep 2020 05:00:43
User entered 'No (N)'	System	12 Sep 2020 05:00:43

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T22:00:38', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '994300a2-4884-490e-81fb-5a6087d41740'	System	12 Sep 2020 05:00:43
User entered '11 Sep 2020 22:00'	System	12 Sep 2020 05:00:43

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 4'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:04', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '49e2c631-ff18-4391-9fca-1695204b7001'	System	13 Sep 2020 05:30:32
User entered 'Yes (Y)'	System	13 Sep 2020 05:30:32

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:12', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '49e2c631-ff18-4391-9fca-1695204b7001'	System	13 Sep 2020 05:30:32
User entered '98.1'	System	13 Sep 2020 05:30:32

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '49e2c631-ff18-4391-9fca-1695204b7001'	System	13 Sep 2020 05:30:32
User entered 'Yes (Y)'	System	13 Sep 2020 05:30:32

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 12:33:25
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication taken for past medical history' (Site from System).	Lauren Arnett (b) (4)	17 Sep 2020 17:56:04
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Sep 2020 05:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '49e2c631-ff18-4391-9fca-1695204b7001'	System	13 Sep 2020 05:30:32
User entered '1'	System	13 Sep 2020 05:30:32

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '49e2c631-ff18-4391-9fca-1695204b7001' User entered '0'	System	13 Sep 2020 05:30:32

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:29', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '49e2c631-ff18-4391-9fca-1695204b7001'	System	13 Sep 2020 05:30:32
User entered '12 Sep 2020 22:30'	System	13 Sep 2020 05:30:32

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 5'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:34', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7fc52a77-2952-4eeb-b1d4-d77f6195c6fe'	System	14 Sep 2020 04:45:50
User entered 'Yes (Y)'	System	14 Sep 2020 04:45:50

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:38', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7fc52a77-2952-4eeb-b1d4-d77f6195c6fe'	System	14 Sep 2020 04:45:50
User entered '98.4'	System	14 Sep 2020 04:45:50

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:42', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7fc52a77-2952-4eeb-b1d4-d77f6195c6fe'	System	14 Sep 2020 04:45:50
User entered 'No (N)'	System	14 Sep 2020 04:45:50

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:46', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7fc52a77-2952-4eeb-b1d4-d77f6195c6fe'	System	14 Sep 2020 04:45:50
User entered '13 Sep 2020 21:45'	System	14 Sep 2020 04:45:50

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 6'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:31', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f95a9803-da1e-4db2-acac-41fe9b1fd603'	System	15 Sep 2020 01:03:44
User entered 'Yes (Y)'	System	15 Sep 2020 01:03:44

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:36', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f95a9803-da1e-4db2-acac-41fe9b1fd603'	System	15 Sep 2020 01:03:44
User entered '98.9'	System	15 Sep 2020 01:03:44

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:39', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f95a9803-da1e-4db2-acac-41fe9b1fd603'	System	15 Sep 2020 01:03:44
User entered 'No (N)'	System	15 Sep 2020 01:03:44

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f95a9803-da1e-4db2-acac-41fe9b1fd603'	System	15 Sep 2020 01:03:44
User entered '14 Sep 2020 18:03'	System	15 Sep 2020 01:03:44

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 7'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:16', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'b3a1fb8c-d908-4055-8396-3ee4711e1ab5'	System	16 Sep 2020 02:05:31
User entered 'Yes (Y)'	System	16 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:19', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'b3a1fb8c-d908-4055-8396-3ee4711e1ab5'	System	16 Sep 2020 02:05:31
User entered '99.1'	System	16 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:22', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'b3a1fb8c-d908-4055-8396-3ee4711e1ab5'	System	16 Sep 2020 02:05:31
User entered 'No (N)'	System	16 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:26', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'b3a1fb8c-d908-4055-8396-3ee4711e1ab5'	System	16 Sep 2020 02:05:31
User entered '15 Sep 2020 19:05'	System	16 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:32', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '37ab9602-5633-41c8-9fda-1900e0d4eaf7'	System	09 Sep 2020 23:43:52
User entered 'None (1)'	System	09 Sep 2020 23:43:52

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:35', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '37ab9602-5633-41c8-9fda-1900e0d4eaf7'	System	09 Sep 2020 23:43:52
User entered 'No (N)'	System	09 Sep 2020 23:43:52

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:38', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '37ab9602-5633-41c8-9fda-1900e0d4eaf7'	System	09 Sep 2020 23:43:52
User entered 'No (N)'	System	09 Sep 2020 23:43:52

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '37ab9602-5633-41c8-9fda-1900e0d4eaf7'	System	09 Sep 2020 23:43:52
User entered 'None (1)'	System	09 Sep 2020 23:43:52

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:46', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '37ab9602-5633-41c8-9fda-1900e0d4eaf7'	System	09 Sep 2020 23:43:52
User entered '09 Sep 2020 16:43'	System	09 Sep 2020 23:43:52

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 16:27'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 18:57'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 19:52'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 2'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:45', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1fe9cda7-3049-426e-b359-d1910b81c3fe'	System	11 Sep 2020 02:05:06
User entered 'None (1)'	System	11 Sep 2020 02:05:06

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:48', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1fe9cda7-3049-426e-b359-d1910b81c3fe'	System	11 Sep 2020 02:05:06
User entered 'No (N)'	System	11 Sep 2020 02:05:06

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1fe9cda7-3049-426e-b359-d1910b81c3fe'	System	11 Sep 2020 02:05:06
User entered 'No (N)'	System	11 Sep 2020 02:05:06

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:58', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1fe9cda7-3049-426e-b359-d1910b81c3fe'	System	11 Sep 2020 02:05:06
User entered 'None (1)'	System	11 Sep 2020 02:05:06

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1fe9cda7-3049-426e-b359-d1910b81c3fe'	System	11 Sep 2020 02:05:06
User entered '10 Sep 2020 19:05'	System	11 Sep 2020 02:05:06

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 3'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-11T21:43:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fc168b2f-b377-4b1a-a725-a6555cc682dd'	System	12 Sep 2020 04:44:04
User entered 'None (1)'	System	12 Sep 2020 04:44:04

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:43:46', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fc168b2f-b377-4b1a-a725-a6555cc682dd'	System	12 Sep 2020 04:44:04
User entered 'No (N)'	System	12 Sep 2020 04:44:04

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:43:48', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fc168b2f-b377-4b1a-a725-a6555cc682dd'	System	12 Sep 2020 04:44:04
User entered 'No (N)'	System	12 Sep 2020 04:44:04

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-11T21:43:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fc168b2f-b377-4b1a-a725-a6555cc682dd'	System	12 Sep 2020 04:44:04
User entered 'None (1)'	System	12 Sep 2020 04:44:04

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:43:58', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fc168b2f-b377-4b1a-a725-a6555cc682dd'	System	12 Sep 2020 04:44:04
User entered '11 Sep 2020 21:43'	System	12 Sep 2020 04:44:04

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 4'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f50a3003-fc61-4de0-a86a-2586583707a6'	System	13 Sep 2020 05:30:59
User entered 'None (1)'	System	13 Sep 2020 05:30:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f50a3003-fc61-4de0-a86a-2586583707a6'	System	13 Sep 2020 05:30:59
User entered 'No (N)'	System	13 Sep 2020 05:30:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:49', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f50a3003-fc61-4de0-a86a-2586583707a6'	System	13 Sep 2020 05:30:59
User entered 'No (N)'	System	13 Sep 2020 05:30:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:49', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f50a3003-fc61-4de0-a86a-2586583707a6'	System	13 Sep 2020 05:30:59
User entered 'None (1)'	System	13 Sep 2020 05:30:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:56', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f50a3003-fc61-4de0-a86a-2586583707a6'	System	13 Sep 2020 05:30:59
User entered '12 Sep 2020 22:30'	System	13 Sep 2020 05:30:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 5'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '95aa360d-52f4-4126-964f-3a77a71fd7f4'	System	14 Sep 2020 04:46:07
User entered 'None (1)'	System	14 Sep 2020 04:46:07

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:54', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '95aa360d-52f4-4126-964f-3a77a71fd7f4'	System	14 Sep 2020 04:46:07
User entered 'No (N)'	System	14 Sep 2020 04:46:07

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:56', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '95aa360d-52f4-4126-964f-3a77a71fd7f4'	System	14 Sep 2020 04:46:07
User entered 'No (N)'	System	14 Sep 2020 04:46:07

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:59', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '95aa360d-52f4-4126-964f-3a77a71fd7f4'	System	14 Sep 2020 04:46:07
User entered 'None (1)'	System	14 Sep 2020 04:46:07

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '95aa360d-52f4-4126-964f-3a77a71fd7f4'	System	14 Sep 2020 04:46:07
User entered '13 Sep 2020 21:46'	System	14 Sep 2020 04:46:07

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 6'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-14T18:02:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98ae7581-1ae7-4754-a0b1-c678b12a3426'	System	15 Sep 2020 01:02:45
User entered 'None (1)'	System	15 Sep 2020 01:02:45

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:02:32', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98ae7581-1ae7-4754-a0b1-c678b12a3426'	System	15 Sep 2020 01:02:45
User entered 'No (N)'	System	15 Sep 2020 01:02:45

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:02:35', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98ae7581-1ae7-4754-a0b1-c678b12a3426'	System	15 Sep 2020 01:02:45
User entered 'No (N)'	System	15 Sep 2020 01:02:45

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-14T18:02:38', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98ae7581-1ae7-4754-a0b1-c678b12a3426'	System	15 Sep 2020 01:02:45
User entered 'None (1)'	System	15 Sep 2020 01:02:45

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:02:42', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98ae7581-1ae7-4754-a0b1-c678b12a3426'	System	15 Sep 2020 01:02:45
User entered '14 Sep 2020 18:02'	System	15 Sep 2020 01:02:45

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 7'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:30', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5a9a87e6-5206-4495-9226-b9c6d82af47c'	System	16 Sep 2020 02:05:46
User entered 'None (1)'	System	16 Sep 2020 02:05:46

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:33', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5a9a87e6-5206-4495-9226-b9c6d82af47c'	System	16 Sep 2020 02:05:46
User entered 'No (N)'	System	16 Sep 2020 02:05:46

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:36', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5a9a87e6-5206-4495-9226-b9c6d82af47c'	System	16 Sep 2020 02:05:46
User entered 'No (N)'	System	16 Sep 2020 02:05:46

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:39', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5a9a87e6-5206-4495-9226-b9c6d82af47c'	System	16 Sep 2020 02:05:46
User entered 'None (1)'	System	16 Sep 2020 02:05:46

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5a9a87e6-5206-4495-9226-b9c6d82af47c'	System	16 Sep 2020 02:05:46
User entered '15 Sep 2020 19:05'	System	16 Sep 2020 02:05:46

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:52', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'None (0)'	System	09 Sep 2020 23:44:17

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:55', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'None (0)'	System	09 Sep 2020 23:44:17

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:57', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'None (0)'	System	09 Sep 2020 23:44:17

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:44:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'None (0)'	System	09 Sep 2020 23:44:17

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:44:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'None (0)'	System	09 Sep 2020 23:44:17

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:44:04', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'None (0)'	System	09 Sep 2020 23:44:17

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-09T16:44:09', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'No (N)'	System	09 Sep 2020 23:44:17

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:44:12', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered '09 Sep 2020 16:44'	System	09 Sep 2020 23:44:17

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 16:27'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 18:57'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 19:52'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 2'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:08', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered 'None (0)'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:11', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered 'None (0)'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:13', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered 'None (0)'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered 'None (0)'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:19', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered 'None (0)'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:22', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered 'None (0)'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:25', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered 'No (N)'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered '10 Sep 2020 19:05'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 3'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:03', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'None (0)'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:11', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'No interference with activity (1)'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:15', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'None (0)'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'None (0)'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:21', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'None (0)'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'None (0)'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'No (N)'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:30', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered '11 Sep 2020 21:44'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 4'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'None (0)'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:04', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'None (0)'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:07', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'None (0)'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:10', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'None (0)'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:13', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'None (0)'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:15', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'None (0)'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:19', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'No (N)'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:22', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered '12 Sep 2020 22:31'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 5'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:08', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'None (0)'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:10', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'None (0)'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:13', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'None (0)'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:16', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'None (0)'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:18', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'None (0)'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:20', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'None (0)'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'No (N)'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:26', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered '13 Sep 2020 21:46'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 6'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:02:50', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'None (0)'	System	15 Sep 2020 01:03:22

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'None (0)'	System	15 Sep 2020 01:03:22

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:03', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'None (0)'	System	15 Sep 2020 01:03:22

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:05', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'None (0)'	System	15 Sep 2020 01:03:22

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:08', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'None (0)'	System	15 Sep 2020 01:03:22

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:10', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'None (0)'	System	15 Sep 2020 01:03:22

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:14', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'No (N)'	System	15 Sep 2020 01:03:22

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered '14 Sep 2020 18:03'	System	15 Sep 2020 01:03:22

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 7'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:46', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'None (0)'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:54', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'No interference with activity (1)'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'None (0)'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:57', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'None (0)'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:59', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'None (0)'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:06:01', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'None (0)'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-15T19:06:04', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'No (N)'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:06:06', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered '15 Sep 2020 19:06'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 02:06:12
User entered 'Day 8'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-17T10:32:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '339342ab-42eb-4e14-9ee6-27dd6a7fb191'	System	17 Sep 2020 17:33:02
User entered 'None (0)'	System	17 Sep 2020 17:33:02

US3732304

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-17T10:32:56', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '339342ab-42eb-4e14-9ee6-27dd6a7fb191'	System	17 Sep 2020 17:33:02
User entered '17 Sep 2020 10:32'	System	17 Sep 2020 17:33:02

US3732304

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 02:06:12
User entered 'Day 8'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-09-17T10:33:01', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd87c2b6b-48c3-479e-8a80-552a5e2fec03'	System	17 Sep 2020 17:33:09
User entered 'No (N)'	System	17 Sep 2020 17:33:09

US3732304

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-17T10:33:05', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd87c2b6b-48c3-479e-8a80-552a5e2fec03'	System	17 Sep 2020 17:33:09
User entered '17 Sep 2020 10:33'	System	17 Sep 2020 17:33:09

US3732304

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 02:06:12

US3732304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:46
User entered 'Yes (Y)'	Linda Vega (b) (4)	17 Sep 2020 01:01:24
	(b) (4)	

US3732304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:46
User entered '16 Sep 2020'	Linda Vega (b) (4) (b) (4)	17 Sep 2020 01:01:24

US3732304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:46
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	17 Sep 2020 01:01:24

US3732304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:46
User entered empty.	Linda Vega (b) (4) (b) (4)	17 Sep 2020 01:01:24

US3732304

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:57
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	17 Sep 2020 01:01:33

US3732304

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 01:01:33

US3732304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:08:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 01:42:25

US3732304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:08:36
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 01:42:25

US3732304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:08:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 01:42:25

US3732304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:08:36
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 01:42:25

US3732304

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:08:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 01:42:14

US3732304

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 01:42:14

US3732304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:09:37
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	30 Sep 2020 17:34:46

US3732304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:09:37
User entered '30 Sep 2020'	Sylvia Lindholm (b) (4)	30 Sep 2020 17:34:46

US3732304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:09:37
User entered 'Contact Made (CONTACT MADE)'	Sylvia Lindholm (b) (4)	30 Sep 2020 17:34:46

US3732304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:09:37
User entered empty.	Sylvia Lindholm (b) (4)	30 Sep 2020 17:34:46

US3732304

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:09:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Oct 2020 19:36:00

US3732304

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 19:36:00

US3732304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:10:16
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:54:16

US3732304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:10:16
User entered '07 Oct 2020'	Amara Yilmaz (b) (4)	08 Oct 2020 15:54:16
	(b) (4)	

US3732304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:10:16
User entered 'Clinic (Clinic)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:54:16

US3732304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:28

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	08 Oct 2020 15:54:16

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '07 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '13:25'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '07 Oct 2020 13:25'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '97.5' F	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered 'Oral (Oral)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '97'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '16'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '133'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '89'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '07 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '14:56'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '07 Oct 2020 14:56'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '98.7' F	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered 'Oral (Oral)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '96'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '15'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '135'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '87'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:36
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:54:40

US3732304

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:36
User entered '07 Oct 2020'	Amara Yilmaz (b) (4)	08 Oct 2020 15:54:40
	(b) (4)	

US3732304

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:56:07

US3732304

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered '07 Oct 2020'	Amara Yilmaz (b) (4)	08 Oct 2020 15:56:07
	(b) (4)	

US3732304

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Test performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered 'Urine (URINE)'	Amara Yilmaz (b) (4)	08 Oct 2020 15:56:07
	(b) (4)	

US3732304

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Result](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered 'Negative (NEGATIVE)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:56:07

US3732304

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:56:07

US3732304

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Collection date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:56:07

US3732304

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

[Collection time](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered empty.	Amara Yilmaz (b) (4)	08 Oct 2020 15:56:07
	(b) (4)	

US3732304

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 15:56:07

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered empty.	Lauren Arnett (b) (4)	07 Oct 2020 21:29:34
	(b) (4)	

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered '07 Oct 2020'	Lauren Arnett (b) (4)	07 Oct 2020 21:29:34
	(b) (4)	

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered '14:26'	Lauren Arnett (b) (4) (b) (4)	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '07 Oct 2020 14:26'	System	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered 'Right Arm (RIGHT ARM)'	Lauren Arnett (b) (4) (b) (4)	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered 'ONCE'	System	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:28

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:39
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:09

US3732304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:39
User entered '07 Oct 2020'	Amara Yilmaz (b) (4)	08 Oct 2020 15:55:09
	(b) (4)	

US3732304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:39
User entered '14:20'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:09

US3732304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '07 Oct 2020 14:20'	System	08 Oct 2020 15:55:09

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:13:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:47
User entered '07 Oct 2020'	Amara Yilmaz (b) (4)	08 Oct 2020 15:55:28
	(b) (4)	

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:28

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:28

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:47
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	08 Oct 2020 15:55:28
	(b) (4)	

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:47
User entered '13:58'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:28

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '07 Oct 2020 13:58'	System	08 Oct 2020 15:55:28

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:28

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amara Yilmaz (b) (4)	08 Oct 2020 15:55:28

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:47
User entered 'No (N)'	Amara Yilmaz (b) (4)	08 Oct 2020 15:55:28
	(b) (4)	

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:47
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:28

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 15:55:28

US3732304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:54
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:35

US3732304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 15:55:35

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:00:15', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '35808238-29cd-4a7c-90e4-5daf9ac691a5'	System	07 Oct 2020 22:00:50
User entered 'Yes (Y)'	System	07 Oct 2020 22:00:50

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:00:21', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '35808238-29cd-4a7c-90e4-5daf9ac691a5'	System	07 Oct 2020 22:00:50
User entered '98.7'	System	07 Oct 2020 22:00:50

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:00:25', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '35808238-29cd-4a7c-90e4-5daf9ac691a5'	System	07 Oct 2020 22:00:50
User entered 'No (N)'	System	07 Oct 2020 22:00:50

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:00:45', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '35808238-29cd-4a7c-90e4-5daf9ac691a5'	System	07 Oct 2020 22:00:50
User entered '07 Oct 2020 15:00'	System	07 Oct 2020 22:00:50

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 14:46'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 17:16'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:12', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '551924c2-fac9-4fa2-9c88-4e3b5f05e0bb'	System	08 Oct 2020 18:01:35
User entered 'Yes (Y)'	System	08 Oct 2020 18:01:35

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:20', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '551924c2-fac9-4fa2-9c88-4e3b5f05e0bb' User entered '98.1'	System	08 Oct 2020 18:01:35

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '551924c2-fac9-4fa2-9c88-4e3b5f05e0bb'	System	08 Oct 2020 18:01:35
User entered 'No (N)'	System	08 Oct 2020 18:01:35

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '551924c2-fac9-4fa2-9c88-4e3b5f05e0bb'	System	08 Oct 2020 18:01:35
User entered '08 Oct 2020 11:01'	System	08 Oct 2020 18:01:35

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 18:11'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 2'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:31:22', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98f78f96-e11a-4642-819d-57b756f5033f'	System	09 Oct 2020 02:31:38
User entered 'Yes (Y)'	System	09 Oct 2020 02:31:38

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:31:28', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98f78f96-e11a-4642-819d-57b756f5033f'	System	09 Oct 2020 02:31:38
User entered '98.7'	System	09 Oct 2020 02:31:38

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:31:30', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98f78f96-e11a-4642-819d-57b756f5033f'	System	09 Oct 2020 02:31:38
User entered 'No (N)'	System	09 Oct 2020 02:31:38

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:31:34', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98f78f96-e11a-4642-819d-57b756f5033f' User entered '08 Oct 2020 19:31'	System	09 Oct 2020 02:31:38
	System	09 Oct 2020 02:31:38

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 3'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-09T19:45:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f67dd042-f430-42fb-b56d-a1e8754f97e0'	System	10 Oct 2020 02:46:46
User entered 'Yes (Y)'	System	10 Oct 2020 02:46:46

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-09T19:46:36', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f67dd042-f430-42fb-b56d-a1e8754f97e0'	System	10 Oct 2020 02:46:46
User entered '99.1'	System	10 Oct 2020 02:46:46

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-09T19:46:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f67dd042-f430-42fb-b56d-a1e8754f97e0'	System	10 Oct 2020 02:46:46
User entered 'No (N)'	System	10 Oct 2020 02:46:46

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-09T19:46:44', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f67dd042-f430-42fb-b56d-a1e8754f97e0'	System	10 Oct 2020 02:46:46
User entered '09 Oct 2020 19:46'	System	10 Oct 2020 02:46:46

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 4'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:04', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '71e57e2d-8181-4e68-9ecf-21e644e6ad58'	System	11 Oct 2020 02:03:20
User entered 'Yes (Y)'	System	11 Oct 2020 02:03:20

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:09', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '71e57e2d-8181-4e68-9ecf-21e644e6ad58'	System	11 Oct 2020 02:03:20
User entered '99.2'	System	11 Oct 2020 02:03:20

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:13', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '71e57e2d-8181-4e68-9ecf-21e644e6ad58'	System	11 Oct 2020 02:03:20
User entered 'No (N)'	System	11 Oct 2020 02:03:20

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '71e57e2d-8181-4e68-9ecf-21e644e6ad58'	System	11 Oct 2020 02:03:20
User entered '10 Oct 2020 19:03'	System	11 Oct 2020 02:03:20

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 5'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:32', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '9cee6a99-18bb-42c8-8b50-8e542398e1c9'	System	12 Oct 2020 08:42:45
User entered 'Yes (Y)'	System	12 Oct 2020 08:42:45

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:35', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '9cee6a99-18bb-42c8-8b50-8e542398e1c9'	System	12 Oct 2020 08:42:45
User entered '98.5'	System	12 Oct 2020 08:42:45

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:39', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '9cee6a99-18bb-42c8-8b50-8e542398e1c9'	System	12 Oct 2020 08:42:45
User entered 'No (N)'	System	12 Oct 2020 08:42:45

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '9cee6a99-18bb-42c8-8b50-8e542398e1c9'	System	12 Oct 2020 08:42:45
User entered '12 Oct 2020 01:42'	System	12 Oct 2020 08:42:45

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 6'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 7'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:08', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'dda373c0-7c18-4c70-a0f9-3eaa27222d66'	System	13 Oct 2020 20:18:24
User entered 'Yes (Y)'	System	13 Oct 2020 20:18:24

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:14', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'dda373c0-7c18-4c70-a0f9-3eaa27222d66'	System	13 Oct 2020 20:18:24
User entered '98.6'	System	13 Oct 2020 20:18:24

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:18', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'dda373c0-7c18-4c70-a0f9-3eaa27222d66'	System	13 Oct 2020 20:18:24
User entered 'No (N)'	System	13 Oct 2020 20:18:24

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:21', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'dda373c0-7c18-4c70-a0f9-3eaa27222d66'	System	13 Oct 2020 20:18:24
User entered '13 Oct 2020 13:18'	System	13 Oct 2020 20:18:24

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-07T15:00:54', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '2a9a11e0-860e-46ce-be7c-cd9cf68a031a'	System	07 Oct 2020 22:01:18
User entered 'None (1)'	System	07 Oct 2020 22:01:18

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:00:59', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '2a9a11e0-860e-46ce-be7c-cd9cf68a031a'	System	07 Oct 2020 22:01:18
User entered 'No (N)'	System	07 Oct 2020 22:01:18

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '2a9a11e0-860e-46ce-be7c-cd9cf68a031a'	System	07 Oct 2020 22:01:18
User entered 'No (N)'	System	07 Oct 2020 22:01:18

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:07', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '2a9a11e0-860e-46ce-be7c-cd9cf68a031a'	System	07 Oct 2020 22:01:18
User entered 'None (1)'	System	07 Oct 2020 22:01:18

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:10', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '2a9a11e0-860e-46ce-be7c-cd9cf68a031a'	System	07 Oct 2020 22:01:18
User entered '07 Oct 2020 15:01'	System	07 Oct 2020 22:01:18

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 14:46'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 17:16'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:32', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '80a15ce9-0df3-4300-bb98-d7b0e31d2dab'	System	08 Oct 2020 18:01:46
User entered 'None (1)'	System	08 Oct 2020 18:01:46

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:34', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '80a15ce9-0df3-4300-bb98-d7b0e31d2dab'	System	08 Oct 2020 18:01:46
User entered 'No (N)'	System	08 Oct 2020 18:01:46

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:37', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '80a15ce9-0df3-4300-bb98-d7b0e31d2dab'	System	08 Oct 2020 18:01:46
User entered 'No (N)'	System	08 Oct 2020 18:01:46

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:40', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '80a15ce9-0df3-4300-bb98-d7b0e31d2dab'	System	08 Oct 2020 18:01:46
User entered 'None (1)'	System	08 Oct 2020 18:01:46

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:42', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '80a15ce9-0df3-4300-bb98-d7b0e31d2dab' User entered '08 Oct 2020 11:01'	System	08 Oct 2020 18:01:46
	System	08 Oct 2020 18:01:46

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 18:11'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 2'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-08T19:31:50', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a2e20364-02ef-450d-aea9-5c5a0965bba7'	System	09 Oct 2020 02:32:09
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 02:32:09

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:31:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a2e20364-02ef-450d-aea9-5c5a0965bba7'	System	09 Oct 2020 02:32:09
User entered 'No (N)'	System	09 Oct 2020 02:32:09

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a2e20364-02ef-450d-aea9-5c5a0965bba7'	System	09 Oct 2020 02:32:09
User entered 'No (N)'	System	09 Oct 2020 02:32:09

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a2e20364-02ef-450d-aea9-5c5a0965bba7'	System	09 Oct 2020 02:32:09
User entered 'None (1)'	System	09 Oct 2020 02:32:09

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:06', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a2e20364-02ef-450d-aea9-5c5a0965bba7'	System	09 Oct 2020 02:32:09
User entered '08 Oct 2020 19:32'	System	09 Oct 2020 02:32:09

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 3'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:23', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5c6fd80f-cde2-4a63-b794-5e2e7c11afbb'	System	10 Oct 2020 07:00:38
User entered 'None (1)'	System	10 Oct 2020 07:00:38

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5c6fd80f-cde2-4a63-b794-5e2e7c11afbb'	System	10 Oct 2020 07:00:38
User entered 'No (N)'	System	10 Oct 2020 07:00:38

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:30', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5c6fd80f-cde2-4a63-b794-5e2e7c11afbb'	System	10 Oct 2020 07:00:38
User entered 'No (N)'	System	10 Oct 2020 07:00:38

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:33', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5c6fd80f-cde2-4a63-b794-5e2e7c11afbb'	System	10 Oct 2020 07:00:38
User entered 'None (1)'	System	10 Oct 2020 07:00:38

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:36', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5c6fd80f-cde2-4a63-b794-5e2e7c11afbb'	System	10 Oct 2020 07:00:38
User entered '10 Oct 2020 00:00'	System	10 Oct 2020 07:00:38

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 4'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'e14d51a4-b7c6-47ad-a71f-638ac925d51f'	System	11 Oct 2020 02:03:41
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 02:03:41

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:29', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'e14d51a4-b7c6-47ad-a71f-638ac925d51f'	System	11 Oct 2020 02:03:41
User entered 'No (N)'	System	11 Oct 2020 02:03:41

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:33', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'e14d51a4-b7c6-47ad-a71f-638ac925d51f'	System	11 Oct 2020 02:03:41
User entered 'No (N)'	System	11 Oct 2020 02:03:41

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:36', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'e14d51a4-b7c6-47ad-a71f-638ac925d51f'	System	11 Oct 2020 02:03:41
User entered 'None (1)'	System	11 Oct 2020 02:03:41

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:38', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'e14d51a4-b7c6-47ad-a71f-638ac925d51f' User entered '10 Oct 2020 19:03'	System	11 Oct 2020 02:03:41

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 5'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:47', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '133db141-4c1e-4a97-9a20-c7af4946bdbbc'	System	12 Oct 2020 08:43:03
User entered 'Does not interfere with activity (2)'	System	12 Oct 2020 08:43:03

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:49', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '133db141-4c1e-4a97-9a20-c7af4946bdbc'	System	12 Oct 2020 08:43:03
User entered 'No (N)'	System	12 Oct 2020 08:43:03

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '133db141-4c1e-4a97-9a20-c7af4946bdbc'	System	12 Oct 2020 08:43:03
User entered 'No (N)'	System	12 Oct 2020 08:43:03

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:57', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '133db141-4c1e-4a97-9a20-c7af4946bdbc'	System	12 Oct 2020 08:43:03
User entered 'None (1)'	System	12 Oct 2020 08:43:03

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:59', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '133db141-4c1e-4a97-9a20-c7af4946bdbc'	System	12 Oct 2020 08:43:03
User entered '12 Oct 2020 01:42'	System	12 Oct 2020 08:43:03

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 6'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 7'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:30', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7784a56f-fb4f-4861-b57d-bc7ad55efd03'	System	13 Oct 2020 20:18:47
User entered 'Does not interfere with activity (2)'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:33', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7784a56f-fb4f-4861-b57d-bc7ad55efd03'	System	13 Oct 2020 20:18:47
User entered 'No (N)'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:36', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7784a56f-fb4f-4861-b57d-bc7ad55efd03'	System	13 Oct 2020 20:18:47
User entered 'No (N)'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:39', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7784a56f-fb4f-4861-b57d-bc7ad55efd03'	System	13 Oct 2020 20:18:47
User entered 'None (1)'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7784a56f-fb4f-4861-b57d-bc7ad55efd03'	System	13 Oct 2020 20:18:47
User entered '13 Oct 2020 13:18'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:14', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'None (0)'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'None (0)'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:19', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'None (0)'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:21', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'None (0)'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'None (0)'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'None (0)'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:35', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'No (N)'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:39', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered '07 Oct 2020 15:01'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 14:46'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 17:16'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:48', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'None (0)'	System	08 Oct 2020 18:02:10

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'None (0)'	System	08 Oct 2020 18:02:10

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'None (0)'	System	08 Oct 2020 18:02:10

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:54', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'None (0)'	System	08 Oct 2020 18:02:10

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:56', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'None (0)'	System	08 Oct 2020 18:02:10

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:58', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'None (0)'	System	08 Oct 2020 18:02:10

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-08T11:02:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'No (N)'	System	08 Oct 2020 18:02:10

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:02:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered '08 Oct 2020 11:02'	System	08 Oct 2020 18:02:10

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 18:11'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 2'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:10', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'None (0)'	System	09 Oct 2020 02:32:32

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:12', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'None (0)'	System	09 Oct 2020 02:32:32

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:14', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'None (0)'	System	09 Oct 2020 02:32:32

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:16', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'None (0)'	System	09 Oct 2020 02:32:32

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'None (0)'	System	09 Oct 2020 02:32:32

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:20', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'None (0)'	System	09 Oct 2020 02:32:32

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'No (N)'	System	09 Oct 2020 02:32:32

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:28', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered '08 Oct 2020 19:32'	System	09 Oct 2020 02:32:32

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 3'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:40', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'None (0)'	System	10 Oct 2020 07:00:57

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'None (0)'	System	10 Oct 2020 07:00:57

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:43', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'None (0)'	System	10 Oct 2020 07:00:57

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:45', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'None (0)'	System	10 Oct 2020 07:00:57

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:47', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'None (0)'	System	10 Oct 2020 07:00:57

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:48', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'None (0)'	System	10 Oct 2020 07:00:57

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'No (N)'	System	10 Oct 2020 07:00:57

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered '10 Oct 2020 00:00'	System	10 Oct 2020 07:00:57

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 4'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:42', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'None (0)'	System	11 Oct 2020 02:03:58

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:44', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'None (0)'	System	11 Oct 2020 02:03:58

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:46', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'None (0)'	System	11 Oct 2020 02:03:58

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:47', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'None (0)'	System	11 Oct 2020 02:03:58

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:49', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'None (0)'	System	11 Oct 2020 02:03:58

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'None (0)'	System	11 Oct 2020 02:03:58

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'No (N)'	System	11 Oct 2020 02:03:58

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:55', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered '10 Oct 2020 19:03'	System	11 Oct 2020 02:03:58

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 5'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:03', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'None (0)'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:06', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'None (0)'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:08', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'None (0)'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:11', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'None (0)'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:13', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'None (0)'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:14', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'None (0)'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'No (N)'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:20', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered '12 Oct 2020 01:43'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 6'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 7'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:45', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered 'None (0)'	System	13 Oct 2020 20:19:05

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:47', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered 'None (0)'	System	13 Oct 2020 20:19:05

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:50', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered 'None (0)'	System	13 Oct 2020 20:19:05

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:52', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered 'None (0)'	System	13 Oct 2020 20:19:05

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:54', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered 'None (0)'	System	13 Oct 2020 20:19:05

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:56', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered 'None (0)'	System	13 Oct 2020 20:19:05

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:58', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered 'No (N)'	System	13 Oct 2020 20:19:05

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:19:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered '13 Oct 2020 13:19'	System	13 Oct 2020 20:19:05

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 20:18:47
User entered 'Day 8'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-14T23:07:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fa1704f9-f277-443c-a7de-c33990d6a5be'	System	15 Oct 2020 06:08:05
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 06:08:05

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 11:13:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-14T23:07:59', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fa1704f9-f277-443c-a7de-c33990d6a5be'	System	15 Oct 2020 06:08:05
User entered '14 Oct 2020 23:07'	System	15 Oct 2020 06:08:05

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 20:18:47
User entered 'Day 9'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(10)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 06:08:05
User entered 'Day 10'	System	15 Oct 2020 06:08:05

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(10)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 06:08:05

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(10)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 06:08:05

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 20:18:47
User entered 'Day 8'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:13:28

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 (ee54f00ecea9d6bb)', Time: '2020-10-14T23:08:03', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '88866545-2951-4597-a82b-8363e527417f'	System	15 Oct 2020 06:08:12
User entered 'No (N)'	System	15 Oct 2020 06:08:12

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:13:28

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-14T23:08:06', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '88866545-2951-4597-a82b-8363e527417f'	System	15 Oct 2020 06:08:12
User entered '14 Oct 2020 23:08'	System	15 Oct 2020 06:08:12

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 20:18:47
User entered 'Day 9'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 06:08:05
User entered 'Day 10'	System	15 Oct 2020 06:08:05

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:13:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 06:08:05

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:13:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 06:08:05

US3732304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:13:48
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	16 Oct 2020 01:36:40

US3732304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:13:48
User entered '15 Oct 2020'	Sylvia Lindholm (b) (4)	16 Oct 2020 01:36:40

US3732304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:13:48
User entered 'Contact Made (CONTACT MADE)'	Sylvia Lindholm (b) (4)	16 Oct 2020 01:36:40

US3732304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:13:48
User entered empty.	Sylvia Lindholm (b) (4)	16 Oct 2020 01:36:40

US3732304

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:13:58
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	16 Oct 2020 01:36:46

US3732304

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 01:36:46

US3732304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:31
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	21 Oct 2020 22:36:37

US3732304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:31
User entered '21 Oct 2020'	Linda Vega (b) (4) (b) (4)	21 Oct 2020 22:36:37

US3732304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:31
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	21 Oct 2020 22:36:37

US3732304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:31
User entered empty.	Linda Vega (b) (4) (b) (4)	21 Oct 2020 22:36:37

US3732304

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:37
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	21 Oct 2020 22:36:41

US3732304

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 22:36:41

US3732304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:48
User entered 'Yes (Y)'	Linda Vega (b) (4)	28 Oct 2020 18:13:55
	(b) (4)	

US3732304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:48
User entered '28 Oct 2020'	Linda Vega (b) (4) (b) (4)	28 Oct 2020 18:13:55

US3732304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:48
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	28 Oct 2020 18:13:55

US3732304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:48
User entered empty.	Linda Vega (b) (4) (b) (4)	28 Oct 2020 18:13:55

US3732304

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:04
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	28 Oct 2020 18:13:46

US3732304

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 18:13:46

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '06 Nov 2020 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '10 Nov 2020 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '13 Nov 2020 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '17 Nov 2020 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 06:53:31

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:13:28

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:16:33
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:49:35

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Pain injection site - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 16:52:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 16:52:21
Data point term sent to Coder	System	19 Oct 2020 16:50:59
User entered 'pain at injection site'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:26:29
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.'	(b) (4), (b) (6)	24 Nov 2020 22:25:27
answered with 'updated ' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:23:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:23:16
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:00:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom PAIN AT INJECTION SITE on 08 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:26:39
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom PAIN AT INJECTION SITE on 08 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated per eDiary start date' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:25:36
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:24:33
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:24:33
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom PAIN AT INJECTION SITE on 08 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '10 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Query 'Data is required. Please provide.' answered with 'time is unknown' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 22:25:45
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Nov 2020 22:25:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Nov 2020 22:25:17
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Nov 2020 22:25:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Nov 2020 22:25:06
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Nov 2020 22:25:06
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:25:06
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	24 Nov 2020 22:25:06
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Nov 2020 22:24:33
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Oct 2020 21:49:41
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	22 Oct 2020 21:49:41
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Oct 2020 21:49:08
User entered '19:32' reason for change: New Information	(b) (4), (b) (6)	22 Oct 2020 21:49:08
User entered empty.	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 22:25:17
User entered '08 Oct 2020 UN:UN' (non-conformant).	System	24 Nov 2020 22:25:06
User entered empty.	System	22 Oct 2020 21:49:41
User entered '10 Oct 2020 19:32'	System	22 Oct 2020 21:49:08
User entered empty.	System	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	22 Oct 2020 21:49:08
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '18 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 21:49:08
User entered empty.	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Query 'Data is required. Please provide.' answered with 'time is unknown' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 22:25:51
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Nov 2020 22:24:33
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'Related (RELATED)'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'Related (RELATED)'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'None (NONE)'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '1'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	22 Oct 2020 21:49:08
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:28

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:16:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:22
User entered 'USA-US102-2020-mRNA-1273-P301000004'	System	04 Nov 2020 16:37:53
User entered 'New'	(b) (4), (b) (6)	04 Nov 2020 16:37:53

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:16:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 20:28:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 20:28:42
Data point term sent to Coder	System	03 Nov 2020 20:28:05
User entered 'bilateral pulmonary embolism'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:16:53
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:36
User entered '29 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:16:57
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:16:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

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 'pending medical records review' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 22:42:00
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)	13 Nov 2020 16:25:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:01
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:06
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:11
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:13
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:44:14
Query 'per CDM RQ: please respond to this query when data is entered' answered with 'pending medical records review' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:42:48
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)	19 Nov 2020 16:58:58
User opened query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 16:58:56
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:15
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 'Awaiting patient's medical records; will complete once records are received.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 20:33:35
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	03 Nov 2020 20:27:56
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:18
User entered '29 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:21
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:22
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:25
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:27
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:29
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:31
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:38
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:40
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: As the last dose of study drug was given on 07 Oct 2020, please update the action taken with study drug from none to not applicable.'	(b) (4), (b) (6)	24 Nov 2020 22:44:32
answered with 'updated' (Site from Safety).		
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:43:57
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:43:34
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:27:29
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:27:29
User opened query 'PV Query: As the last dose of study drug was given on 07 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:24:29
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:42
User entered 'None (NONE)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:45
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:46
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:48
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[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 'pending medical records review' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 22:44:41
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)	13 Nov 2020 16:25:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:54
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:18:00
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'subject notified site yesterday 23NOV2020 of hospital discharge. Medical records are pending at this moment' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 00:01:55
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' answered with 'pending medical records review' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 22:44:53
Query 'PV Query: Please provide date of COVID test if available.' answered with 'pending medical records review' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 22:44:49
Query 'PV Query: Please provide details on 99% occlusion and corresponding test results.' answered with 'pending medical records review' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 22:44:45
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:26:03
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:25:08
User opened query 'PV Query: Please provide date of COVID test if available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:24:12
User opened query 'PV Query: Please provide details on 99% occlusion and corresponding test results.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:24:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:18:04
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Nov 2020 20:37:59

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	03 Nov 2020 20:37:59
User entered 'Subject called site to report above AE and hospitalization from 10/29/20 - ongoing. Subject is admitted at UCSD, medical records will be requested upon subject's return to site. Subject denied any recent travel, smoker or oral BC. Subject reported two negative tests for COVID, performed in hospital. Per subject, unknown cause at this time. Subject stated it was 99% occluded.' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 20:37:59
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Nov 2020 20:27:56
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:28

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 20:27:56

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:13:28

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:22:55
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:55:08

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 10:16:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 10:16:38
Data point term sent to Coder	System	21 Sep 2020 16:59:13
User entered 'zyrtec'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'pet dander and environmental allergies'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:36:57
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:19:40
User entered '10' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:19:35
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:27:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 15:33:46
User entered '3'	Lauren Arnett (b) (4)	21 Sep 2020 16:58:51
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'as needed (PRN)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1978'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:02:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:02:43
Data point term sent to Coder	System	21 Sep 2020 17:01:20
User entered 'albuterol'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'asthma'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '90' reason for change: New Information	Amara Yilmaz (b) (4)	19 Oct 2020 16:43:52
User entered '1'	(b) (4)	
	Lauren Arnett (b) (4)	21 Sep 2020 17:00:35
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User closed query 'Per CDM: Dose Unit is recorded as 'Other - PUFF', however, please confirm if Unit can be selected from already available option PUFF . Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 10:14:32
Query 'Per CDM: Dose Unit is recorded as 'Other - PUFF', however, please confirm if Unit can be selected from already available option PUFF . Thank you.' answered with 'dose unit has been corrected ' (Site from DM).	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:44:17
User entered 'ug (ug)' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:43:52
User opened query 'Per CDM: Dose Unit is recorded as 'Other - PUFF', however, please confirm if Unit can be selected from already available option PUFF . Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 12:45:13
User entered 'Other (OTHER)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty; reason for change New Information	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:43:52
User entered 'puff'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'as needed (PRN)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1974'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:02:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:02:44
Data point term sent to Coder	System	21 Sep 2020 17:01:20
User entered 'pantoprazole'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'gastroesophageal reflux disease'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '20'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1998'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:03:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:03:49
Data point term sent to Coder	System	21 Sep 2020 17:02:22
User entered 'gabapentin'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Sep 2020 17:01:57
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'chronic back pain'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '1200'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4)	21 Sep 2020 17:01:57
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:04:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:04:40
Data point term sent to Coder	System	21 Sep 2020 17:03:24
User entered 'norco'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'post surgical pain'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '10/325'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'as needed (PRN)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:54:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:54:45
Data point term sent to Coder Coding entries removed.	System Lauren Arnett (b) (4) (b) (4)	03 Nov 2020 00:22:53 03 Nov 2020 00:22:01
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 11:30:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 11:30:42
Data point term sent to Coder User entered 'estradiol 0.01% cream'	System Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:28 21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:37:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'entry error updated' (Site from DM).	Lauren Arnett (b) (4)	03 Nov 2020 00:22:31
User entered 'peri-menopause' reason for change: Per Query Resolution	(b) (4)	03 Nov 2020 00:22:01
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 15:34:39
User entered 'frequent urinary tract infections'	Lauren Arnett (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '1'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Other (OTHER)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'pump'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'every other day (QOD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Topical (TOPICAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 2017'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:34:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:34:02
Data point term sent to Coder	System	07 Nov 2020 00:18:18
Coding entries removed.	(b) (4), (b) (6)	07 Nov 2020 00:18:10
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:05:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:05:43
Data point term sent to Coder	System	21 Sep 2020 17:04:30
User entered 'nuva ring'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:38:03
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:18:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:18:10
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:29:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 15:35:26
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:18:10
User entered 'Pregnancy' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:18:10
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'birth control'	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '1'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Other (OTHER)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'ring'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'every month (QM)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Vaginal (VAGINAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 2018'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 21:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 21:42:54
Data point term sent to Coder	System	21 Sep 2020 17:10:45
User entered 'amitriptyline'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'depression / insomnia'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '10'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1996'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:11:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:11:49
Data point term sent to Coder	System	21 Sep 2020 17:10:46
User entered 'fluoxetine'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'depression'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '50'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1996'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:12:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:12:52
Data point term sent to Coder	System	21 Sep 2020 17:11:47
User entered 'wellbutrin'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'depression'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '450'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4)	21 Sep 2020 17:11:01
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1996'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4)	21 Sep 2020 17:11:01
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:44:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:44:28
Data point term sent to Coder	System	07 Nov 2020 00:22:20
Coding entries removed.	(b) (4), (b) (6)	07 Nov 2020 00:21:51
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:12:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:12:52
Data point term sent to Coder	System	21 Sep 2020 17:11:48
User entered 'magnesium'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:38:26
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:21:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:21:51
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:29:23
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 15:36:00
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:21:51
User entered 'VITAMIN deficiency' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:21:51
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'vitamin supplement'	Lauren Arnett (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '1'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'tablet (TABLET)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1998'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 00:23:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 00:23:23
Data point term sent to Coder	System	07 Nov 2020 00:22:20
Coding entries removed.	(b) (4), (b) (6)	07 Nov 2020 00:22:08
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 19:11:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 19:11:51
Data point term sent to Coder	System	22 Sep 2020 19:10:21
User entered 'multivitamin'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:38:41
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:22:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:22:08
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:29:43
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 15:36:33
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:22:08
User entered 'VITAMIN deficiency' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:22:08
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'vitamin supplement'	Lauren Arnett (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '1'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'tablet (TABLET)'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1998'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 00:24:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 00:24:23
Data point term sent to Coder	System	07 Nov 2020 00:23:20
Coding entries removed.	(b) (4), (b) (6)	07 Nov 2020 00:22:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 17:22:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 17:22:53
Data point term sent to Coder	System	24 Sep 2020 17:21:14
User entered 'vitamin D3'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:22:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:22:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Amara Yilmaz (b) (4)	24 Sep 2020 17:20:38
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:22:25
User entered 'VITAMIN deficiency' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:22:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'vitamin supplement'	Amara Yilmaz (b) (4)	24 Sep 2020 17:20:38
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '1'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'tablet (TABLET)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1998'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 00:25:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 00:25:24
Data point term sent to Coder	System	07 Nov 2020 00:24:23
Coding entries removed.	(b) (4), (b) (6)	07 Nov 2020 00:23:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 17:22:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 17:22:54
Data point term sent to Coder	System	24 Sep 2020 17:22:17
User entered 'Zinc'	Amara Yilmaz (b) (4)	24 Sep 2020 17:21:48
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:38:53
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:23:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:23:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 15:41:09
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:23:40
User entered 'VITAMIN deficiency' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:23:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'vitamin supplement'	Amara Yilmaz (b) (4)	24 Sep 2020 17:21:48
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:39:00
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated. entry error' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:23:54
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:23:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:30:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 15:41:42
User entered '1'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:23:40
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:23:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'tablet (TABLET)'	Amara Yilmaz (b) (4)	24 Sep 2020 17:21:48
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1998'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:05:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:05:18
Data point term sent to Coder	System	03 Nov 2020 20:45:46
User entered 'heparin'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'bilateral pulmonary embolism'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '50'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mL (mL)'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'drip'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '29 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:49:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:49:56
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:49:56
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:49:56
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 23:53:58
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 23:53:58
Data point term sent to Coder	System	24 Nov 2020 22:51:26
User entered 'Eloquis'	(b) (4), (b) (6) (b) (4)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[Indication](#)

Audit	User	Time (GMT)
User entered 'SAE- Bilateral Pulmonary Embolism'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

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

Audit	User	Time (GMT)
User entered '03 Nov 2020'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 22:50:51

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'USA-US102-2020-MRNA-1273-P301000004'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Scott'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Overcash'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '5565 Grossmont Center Dr'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'La Mesa'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'CA'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '91942'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered 'US'	System	04 Nov 2020 16:39:02

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 16:39:02

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'USA-US102-2020-MRNA-1273-P301000004'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Scott'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Overcash'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '5565 Grossmont Center Dr'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'La Mesa'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'CA'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '91942'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered 'US'	System	04 Nov 2020 16:39:02

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 16:39:02

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:13:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered '04/Nov/2020 16:38'	System	04 Nov 2020 16:39:02

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:13:28

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered '1'	(b) (4), (b) (6)	04 Nov 2020 16:39:02