

US3512063 (Prod: Jacksonville Center for Clinical Research Center)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:28:54

All time stamps listed in this document are displayed in GMT

US3512063

Form: Participant Creation

Generated On: 26 Nov 2020 09:28:54

[Participant ID](#)

US3512063

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

US3512063

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 AUG 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 09:28:54

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
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 09:28:54

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 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 09:28:54

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:28:54

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:54

Condition	ALLERGY TO CLINDAMYCIN
Start date (dd MMM yyyy)	24 JUL 2020
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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:54

Condition	FOOD ALLERGY
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:54

Condition	SEASONAL ALLERGY
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:54

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN NOV 2005
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)	NOV 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:54

Condition	HEARTBURN
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 (6)

Generated On: 26 Nov 2020 09:28:54

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN SEP 2019
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)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:54

Condition	NEARSIGHTED
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 09:28:54

Condition	CHRONIC INTERMITTENT EAR INFECTION BILATERAL
Start date (dd MMM yyyy)	UN SEP 2019
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)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:54

Condition	CARPAL TUNNEL SYNDROME BILATERAL
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:54

Condition	SCIATICA LEFT SIDE
Start date (dd MMM yyyy)	UN JUN 2016
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)	JUN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:28:54

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:28:54

Condition	RASH OVER ENTIRE BODY
Start date (dd MMM yyyy)	24 JUL 2020
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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:28:54

Condition	BILATERAL CARPAL TUNNEL SURGERY
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:28:54

Condition	OSTEOARTHRITIS BILATERAL KNEES
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:28:54

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:28:54

Condition	FRACTURE NOSE
Start date (dd MMM yyyy)	UN UNK 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1993
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	JAN 1993
Stop Year (derived)	1993

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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:28:54

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:28:54

Condition	OVERWEIGHT
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:28:54

Condition	EDEMA LOWER EXTREMITIES
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:28:54

Condition	TOOTH INFECTION
Start date (dd MMM yyyy)	20 JUL 2020
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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:28:54

Condition	SMOKER
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:28:54

Condition	OSTEOARTHRITIS RIGHT BIG TOE
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:28:54

Condition	OSTEOARTHRITIS BILATERAL SHOULDERS
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:17 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 14:17
Height (<i>xxx.x</i>)	63 in
Weight (<i>xxx.x</i>)	214.8 lb
BMI (<i>xxx.x</i>)	38.12967 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 09:28:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:28:54

Date of assessment (*dd MMM yyyy*) 13 AUG 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 09:28:54

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	13 AUG 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 09:28:54

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 09:28:54

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 AUG 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 09:28:54

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 103957

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 09:28:54

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 09:28:54

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)	13 AUG 2020
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 13:45
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 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 09:28:54

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)	13 AUG 2020
Time of assessment (00:00-23:59)	15:18 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 15:18
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:54

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 09:28:54

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 09:28:54

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)	13 AUG 2020
What was the treatment time? (00:00-23:59)	14:48 (24 HR)
Treatment Date and Time (derived)	13 AUG 2020 14:48
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 09:28:54

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	13 AUG 2020
Collection time (<i>00:00-23:59</i>)	14:06 (24 HR)
Collection date and time (derived)	13 AUG 2020 14:06

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:54

Collection date (<i>dd MMM yyyy</i>)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:17	13 AUG 2020 14:17
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

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 09:28:54

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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 AUG 2020 15:21

PC Open Date & Time 13 AUG 2020 15:08

PC Close Date & Time 13 AUG 2020 17:38

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

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 98.2 °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	14 AUG 2020 11:33
PC Open Date & Time	13 AUG 2020 18:33
PC Close Date & Time	14 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 11:01

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 11:28

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:54

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**

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 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:54

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:19

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 10:16

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

20 AUG 2020 09:10

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

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

13 AUG 2020 15:22

PC Open Date & Time

13 AUG 2020 15:08

PC Close Date & Time

13 AUG 2020 17:38

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

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

14 AUG 2020 11:34

PC Open Date & Time

13 AUG 2020 18:33

PC Close Date & Time

14 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:54

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

15 AUG 2020 11:01

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:54

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

16 AUG 2020 11:29

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:54

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 ☐

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

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:54

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

17 AUG 2020 12:19

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:54

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

19 AUG 2020 10:17

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:54

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

20 AUG 2020 09:10

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 15:23
PC Open Date & Time	13 AUG 2020 15:08
PC Close Date & Time	13 AUG 2020 17:38

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 11:34
PC Open Date & Time	13 AUG 2020 18:33
PC Close Date & Time	14 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:54

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 ☒

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:54

Yes ☐	
PC Time stamp	15 AUG 2020 11:02
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:54

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 ☒

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:54

Yes ☐	
PC Time stamp	16 AUG 2020 11:30
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:54

	Yes ☐
PC Time stamp	
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:54

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 ☒

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:54

Yes ☐	
PC Time stamp	17 AUG 2020 12:20
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:54

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 ☒

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:54

Yes ☐	
PC Time stamp	19 AUG 2020 10:17
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:54

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 ☒

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:54

Yes ☐	
PC Time stamp	20 AUG 2020 09:36
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3512063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

Was Contact Attempted?

Yes ☒

No ☐

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

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512063

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512063

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512063

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	11:11 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:11
Temperature (xxx.x)	97.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3512063

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	10 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

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? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3512063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	10 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:27 (24 HR)
Collection date and time (derived)	10 SEP 2020 11:27

US3512063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:54

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:18	10 SEP 2020 11:18
Nasopharyngeal Swab 2	No		

US3512063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512063

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

Was Contact Attempted?

Yes ☒

No ☐

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

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512063

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512063

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	8 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:26 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 11:26
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:54

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.

US3512063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	8 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:35 (24 HR)
Collection date and time (derived)	8 OCT 2020 11:35

US3512063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 OCT 2020 07:41:12
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 01:22:27

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 05:41:03

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 03:21:33

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 03:41:58

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2020 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2020 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 09:52:42

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2020 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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°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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

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03 FEB 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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10 FEB 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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31 MAR 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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17 APR 2021 00:01

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21 APR 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

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09 FEB 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

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16 FEB 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 APR 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 APR 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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27 APR 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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30 APR 2022 00:01

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04 MAY 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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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07 MAY 2022 00:01

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11 MAY 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

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08 JUN 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

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22 JUN 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

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10 AUG 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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 ☐

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3512063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512063

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512063

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3512063

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:54

Date of Contact	13 AUG 2020
Time of Contact	14:06
Date and Time of Contact (derived)	13 AUG 2020 14:06
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 ☒

US3512063

Folder: Covid-19 Assessment 13 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:28:54

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

US3512063

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:28:54

Did the participant experience any adverse events?

Yes ☐

No ☐

If Yes, enter details on the Adverse Events form.

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:28:54

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

Yes ☒

No ☐

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

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROIDISM
Dose per administration	100
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MCG
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 ☐

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

	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 2004
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	☒

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	HEARTBURN
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 ☐ Intramuscular ☐

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

	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 2015
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	☒

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

Name of Medication	VITAMIN D
Prophylaxis	Yes ☐ No ☒
Indication	VITAMIN D DEFICIENCY
Dose per administration	2000
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 ☐

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

	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 2019
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

Name of Medication	TURMERIC
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

	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 NOV 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS
Dose per administration	800
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

	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 SEP 2019
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

Name of Medication 24 HOUR ALLEGRA D

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 ☐

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

	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 2019
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

Name of Medication	FLONASE
Prophylaxis	Yes ☐ No ☒
Indication	SEASONAL ALLERGIES
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	SPRAY
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 ☐

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

	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)		01 AUG 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3512063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:28:54

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3512063

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:28:54

Date of dosing discontinuation (dd MMM yyyy)

13 AUG 2020

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

US3512063

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:28:54

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 ☐

Audit

US3512063 (Prod: Jacksonville Center for Clinical Research Center)

US3512063

Form: Participant Creation

Generated On: 26 Nov 2020 09:28:54

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3512063'	RWS_ENDPOINT ENDPOINT (b) (4) 	13 Aug 2020 17:50:28

US3512063

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:02

US3512063

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 17:50:29

US3512063

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:02

US3512063

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	13 Aug 2020 19:03:02

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1974'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 17:50:30

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

[Age](#)

Audit	User	Time (GMT)
User entered '46'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:36

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	13 Aug 2020 19:03:36

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '46'	System	13 Aug 2020 19:03:50

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:36

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:36

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

[White](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:36

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

[Black](#)

Audit	User	Time (GMT)
User entered '1'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:36

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:36

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:36

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:36

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:36

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:36

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

Unknown

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:36

US3512063

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:54

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:36

US3512063

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:50

US3512063

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	13 Aug 2020 19:03:50

US3512063

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Aug 2020 19:03:50

US3512063

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:54

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:50

US3512063

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:50

US3512063

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:50

US3512063

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:50

US3512063

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:54

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:50

US3512063

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 17:50:29

US3512063

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:54

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:03:55

US3512063

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:03:55

US3512063

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:28:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 19:58:48

US3512063

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:04:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:04:09
Data point term sent to Coder	System	13 Aug 2020 20:03:28
User entered 'allergy to clindamycin'	Brenda Anderson (b) (4)	13 Aug 2020 20:03:22

US3512063

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '24 Jul 2020'	Brenda Anderson (b) (4)	13 Aug 2020 20:03:22
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:03:22

US3512063

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:03:22

US3512063

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:03:22
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:03:22

US3512063

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	13 Aug 2020 20:03:22

US3512063

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Aug 2020 20:03:22

US3512063

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:03:22

US3512063

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:03:22

US3512063

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Food allergy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:06:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:06:14
Data point term sent to Coder	System	13 Aug 2020 20:05:30
User entered 'food allergy'	Brenda Anderson (b) (4)	13 Aug 2020 20:05:18

US3512063

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 20:30:35
User entered 'UN UNK 1994' reason for change: Data Entry Error	Brenda Anderson (b) (4)	13 Aug 2020 20:30:35
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 20:05:18
User entered 'un UNK ' (non-conformant).	Brenda Anderson (b) (4)	13 Aug 2020 20:05:18

US3512063

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:05:18

US3512063

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:05:18

US3512063

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:05:18
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:05:18

US3512063

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	13 Aug 2020 20:30:35
User entered empty.	System	13 Aug 2020 20:05:18

US3512063

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '1994'	System	13 Aug 2020 20:30:35
User entered empty.	System	13 Aug 2020 20:05:18

US3512063

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:05:18

US3512063

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:05:18

US3512063

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:07:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:07:15
Data point term sent to Coder	System	13 Aug 2020 20:06:30
User entered 'seasonal allergy'	Brenda Anderson (b) (4)	13 Aug 2020 20:06:04

US3512063

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 20:31:04
User entered 'un UNK 1994' reason for change: Data Entry Error	Brenda Anderson (b) (4)	13 Aug 2020 20:31:04
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 20:06:04
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:06:04

US3512063

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:06:04

US3512063

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:06:04

US3512063

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:06:04

US3512063

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:06:04

US3512063

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	13 Aug 2020 20:31:04
User entered empty.	System	13 Aug 2020 20:06:04

US3512063

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '1994'	System	13 Aug 2020 20:31:04
User entered empty.	System	13 Aug 2020 20:06:04

US3512063

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:06:04

US3512063

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:06:04

US3512063

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
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: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:08:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:08:18
Data point term sent to Coder	System	13 Aug 2020 20:07:34
User entered 'acid reflux'	Brenda Anderson (b) (4)	13 Aug 2020 20:07:00

US3512063

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un Nov 2005'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:00

US3512063

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:00

US3512063

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:00

US3512063

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:00

US3512063

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:00

US3512063

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Nov 2005'	System	13 Aug 2020 20:07:00

US3512063

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2005'	System	13 Aug 2020 20:07:00

US3512063

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:07:00

US3512063

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:07:00

US3512063

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:08:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:08:16
Data point term sent to Coder	System	13 Aug 2020 20:07:35
User entered 'heartburn'	Brenda Anderson (b) (4)	13 Aug 2020 20:07:26

US3512063

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:26

US3512063

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:26

US3512063

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:26

US3512063

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:26

US3512063

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:26

US3512063

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	13 Aug 2020 20:07:26

US3512063

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2015'	System	13 Aug 2020 20:07:26

US3512063

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:07:26

US3512063

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:07:26

US3512063

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 00:07:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 00:07:20
Data point term sent to Coder	System	08 Oct 2020 20:51:40
Coding entries removed.	Brenda Anderson (b) (4)	08 Oct 2020 20:51:36
User entered 'VITAMIN D DEFICIENCY' reason for change: Data Entry Error	Brenda Anderson (b) (4)	08 Oct 2020 20:51:36
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Vitamin deficiencies NEC, PT: Hypovitaminosis, LLT: Vitamin deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:10:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:10:12
Data point term sent to Coder	System	13 Aug 2020 20:08:38
User entered 'vitamin deficiency'	Brenda Anderson (b) (4)	13 Aug 2020 20:07:58

US3512063

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un Sep 2019'	Brenda Anderson (b) (4)	13 Aug 2020 20:07:58
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:58

US3512063

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:58

US3512063

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:58

US3512063

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:07:58

US3512063

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Sep 2019'	System	13 Aug 2020 20:07:58

US3512063

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2019'	System	13 Aug 2020 20:07:58

US3512063

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:07:58

US3512063

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:07:58

US3512063

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:10:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:10:14
Data point term sent to Coder	System	13 Aug 2020 20:08:38
User entered 'nearsighted'	Brenda Anderson (b) (4)	13 Aug 2020 20:08:36

US3512063

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:08:36

US3512063

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:08:36

US3512063

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:08:36

US3512063

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:08:36
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:08:36

US3512063

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	13 Aug 2020 20:08:36

US3512063

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2010'	System	13 Aug 2020 20:08:36

US3512063

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:08:36

US3512063

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:08:36

US3512063

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Ear infection, LLT: Ear infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 22:18:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 22:18:26
User closed query 'Per DM CLR: Please specify the laterality of CHRONIC EAR INFECTION (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:27:39
User closed query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:27:36
Data point term sent to Coder	System	01 Oct 2020 16:14:17
Query 'Per DM CLR: Please specify the laterality of CHRONIC EAR INFECTION (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' answered with 'data updated' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 16:13:58
User entered 'CHRONIC INTERMITTENT EAR INFECTION bilateral' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 16:13:54
Query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'the condition is intermittent and the subject has not had an occurrence since the signing of informed consent. There are currently no meds to be reported for this condition. data confirmed as is ' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 12:59:39
Data point term sent to Coder	System	01 Oct 2020 12:59:20
Coding entries removed.	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 12:58:30

US3512063

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User entered 'CHRONIC intermittent EAR INFECTION' reason for change: Data Entry Error	Taylor Johnson (b) (4)	01 Oct 2020 12:58:30
User opened query 'Per DM CLR: Please specify the laterality of CHRONIC EAR INFECTION (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Sep 2020 14:41:55
User opened query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 14:41:44
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Ear infection, LLT: Ear infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 21:15:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 21:15:16
Data point term sent to Coder	System	13 Aug 2020 20:09:41
User entered 'chronic ear infection'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:09:37

US3512063

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN Sep 2019' reason for change: Data Entry Error	Brenda Anderson (b) (4)	13 Aug 2020 20:32:21
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 20:32:14
User entered 'un UNK 2019' reason for change: Data Entry Error	Brenda Anderson (b) (4)	13 Aug 2020 20:32:14
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 20:11:08
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 20:11:08
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	13 Aug 2020 20:11:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 20:09:37
User entered ' n' (non-conformant).	Brenda Anderson (b) (4)	13 Aug 2020 20:09:37

US3512063

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:09:37

US3512063

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:09:37

US3512063

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:09:37

US3512063

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:09:37

US3512063

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Sep 2019'	System	13 Aug 2020 20:32:21
User entered 'Jan 2019'	System	13 Aug 2020 20:32:14
User entered empty.	System	13 Aug 2020 20:09:37

US3512063

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2019'	System	13 Aug 2020 20:32:14
User entered empty.	System	13 Aug 2020 20:09:37

US3512063

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:09:37

US3512063

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:09:37

US3512063

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the laterality of CARPAL TUNNEL SYNDROME (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:27:50
User coded data point as SOC: Nervous system disorders, HLT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 13:02:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	01 Oct 2020 13:02:42
Data point term sent to Coder	System	01 Oct 2020 13:02:23
Query 'Per DM CLR: Please specify the laterality of CARPAL TUNNEL SYNDROME (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. ' answered with 'data updated' (Site from DM).	Taylor Johnson (b) (4)	01 Oct 2020 13:01:36
Coding entries removed.	(b) (4)	
User entered 'CARPAL TUNNEL SYNDROME bilateral' reason for change: Data Entry Error	Taylor Johnson (b) (4)	01 Oct 2020 13:01:26
User opened query 'Per DM CLR: Please specify the laterality of CARPAL TUNNEL SYNDROME (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 14:45:13
User coded data point as SOC: Nervous system disorders, HLT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 20:12:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	13 Aug 2020 20:12:06
Data point term sent to Coder	System	13 Aug 2020 20:11:42
User entered 'carpal tunnel syndrome'	Brenda Anderson (b) (4)	13 Aug 2020 20:11:40

US3512063

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 2008'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:11:40

US3512063

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:11:40

US3512063

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 20:31:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 20:31:32
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	13 Aug 2020 20:31:32
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 20:11:40
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:11:40

US3512063

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 2008' reason for change:	Brenda Anderson (b) (4)	13 Aug 2020 20:31:32
Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:11:40
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:11:40

US3512063

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	13 Aug 2020 20:11:40

US3512063

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2008'	System	13 Aug 2020 20:11:40

US3512063

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	13 Aug 2020 20:31:32
User entered empty.	System	13 Aug 2020 20:11:40

US3512063

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2008'	System	13 Aug 2020 20:31:32
User entered empty.	System	13 Aug 2020 20:11:40

US3512063

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the laterality of SCIATICA (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:27:58
User coded data point as SOC: Nervous system disorders, HLG: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 16:14:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	01 Oct 2020 16:14:55
Data point term sent to Coder	System	01 Oct 2020 16:14:21
Coding entries removed.	Taylor Johnson (b) (4)	01 Oct 2020 16:14:20
User entered 'SCIATICA left side' reason for change: Data Entry Error	(b) (4)	
Query 'Per DM CLR: Please specify the laterality of SCIATICA (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. ' answered with 'daTA UPDQATED' (Site from DM).	Taylor Johnson (b) (4)	01 Oct 2020 16:14:20
User opened query 'Per DM CLR: Please specify the laterality of SCIATICA (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. ' (Site from DM).	(b) (4)	
User entered 'sciatica'	Taylor Johnson (b) (4)	01 Oct 2020 16:14:13
User opened query 'Per DM CLR: Please specify the laterality of SCIATICA (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. ' (Site from DM).	(b) (4)	
User entered 'sciatica'	(b) (4), (b) (6)	27 Sep 2020 14:46:02
User coded data point as SOC: Nervous system disorders, HLG: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 20:14:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	13 Aug 2020 20:14:12
Data point term sent to Coder	System	13 Aug 2020 20:12:44
User entered 'sciatica'	Brenda Anderson (b) (4)	13 Aug 2020 20:12:33

US3512063

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un Jun 2016'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:12:33

US3512063

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:12:33

US3512063

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	13 Aug 2020 20:12:33
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:12:33

US3512063

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:12:33

US3512063

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jun 2016'	System	13 Aug 2020 20:12:33

US3512063

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2016'	System	13 Aug 2020 20:12:33

US3512063

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:12:33

US3512063

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:12:33

US3512063

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:14:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:14:12
Data point term sent to Coder	System	13 Aug 2020 20:13:46
User entered 'sleep apnea'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:13:27

US3512063

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:13:27

US3512063

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:13:27

US3512063

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:13:27

US3512063

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:13:27

US3512063

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:13:27

US3512063

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	13 Aug 2020 20:13:27

US3512063

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2005'	System	13 Aug 2020 20:13:27

US3512063

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:13:27

US3512063

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:13:27

US3512063

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Generalised rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 09:25:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 09:25:20
Data point term sent to Coder	System	13 Aug 2020 20:15:50
User entered 'rash over entire body'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:14:55

US3512063

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 20:29:29
User entered '24 Jul 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4)	13 Aug 2020 20:29:29
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 20:14:55
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:14:55

US3512063

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:14:55

US3512063

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:14:55

US3512063

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:14:55

US3512063

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:14:55

US3512063

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	13 Aug 2020 20:29:29
User entered empty.	System	13 Aug 2020 20:14:55

US3512063

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Aug 2020 20:29:29
User entered empty.	System	13 Aug 2020 20:14:55

US3512063

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:14:55

US3512063

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:14:55

US3512063

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
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)	13 Aug 2020 20:16:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:16:14
Data point term sent to Coder	System	13 Aug 2020 20:15:51
User entered 'bilateral carpal tunnel surgery'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:15:51

US3512063

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 2008'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:15:51

US3512063

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4)	13 Aug 2020 20:15:51
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	13 Aug 2020 20:15:51
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 2008'	Brenda Anderson (b) (4)	13 Aug 2020 20:15:51
	(b) (4)	

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:15:51

US3512063

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	13 Aug 2020 20:15:51

US3512063

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2008'	System	13 Aug 2020 20:15:51

US3512063

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	13 Aug 2020 20:15:51

US3512063

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2008'	System	13 Aug 2020 20:15:51

US3512063

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User closed query ""	(b) (4), (b) (6)	06 Oct 2020 03:28:14
Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable."		
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 13:07:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	01 Oct 2020 13:07:48
Data point term sent to Coder	System	01 Oct 2020 13:07:32
Query ""	Taylor Johnson (b) (4)	01 Oct 2020 13:07:14
Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable."	(b) (4)	
' answered with 'data updated' (Site from DM).		
Coding entries removed.	Taylor Johnson (b) (4)	01 Oct 2020 13:07:00
User entered 'OSTEOARTHRITIS bilateral knees' reason for change: Data Entry Error	(b) (4)	
User opened query ""	Taylor Johnson (b) (4)	01 Oct 2020 13:07:00
Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable."	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 14:46:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.		
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 20:19:18
Data point term sent to Coder	(b) (4)	
User entered 'osteoarthritis'	System	13 Aug 2020 20:17:56
	Brenda Anderson (b) (4)	13 Aug 2020 20:16:59
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 1993'	Brenda Anderson (b) (4)	13 Aug 2020 20:16:59
	(b) (4)	

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:16:59

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:16:59

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:16:59

US3512063

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:16:59

US3512063

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 1993'	System	13 Aug 2020 20:16:59

US3512063

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '1993'	System	13 Aug 2020 20:16:59

US3512063

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:16:59

US3512063

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:16:59

US3512063

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
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: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:19:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:19:18
Data point term sent to Coder	System	13 Aug 2020 20:17:57
User entered 'back pain'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:17:48

US3512063

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:17:48

US3512063

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:17:48

US3512063

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:17:48

US3512063

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:17:48

US3512063

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:17:48

US3512063

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	13 Aug 2020 20:17:48

US3512063

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2000'	System	13 Aug 2020 20:17:48

US3512063

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:17:48

US3512063

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:17:48

US3512063

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Fractured nose - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:06:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:06:23
Data point term sent to Coder	System	13 Aug 2020 20:33:39
User entered 'fracture nose'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:33:33

US3512063

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 1993'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:33:33

US3512063

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:33:33

US3512063

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:33:33

US3512063

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 1993'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:33:33

US3512063

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:33:33

US3512063

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 1993'	System	13 Aug 2020 20:33:33

US3512063

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '1993'	System	13 Aug 2020 20:33:33

US3512063

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 1993'	System	13 Aug 2020 20:33:33

US3512063

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '1993'	System	13 Aug 2020 20:33:33

US3512063

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:40:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:40:06
Data point term sent to Coder	System	13 Aug 2020 20:39:07
User entered 'hypothyroidism'	Brenda Anderson (b) (4)	13 Aug 2020 20:38:58

US3512063

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:38:58

US3512063

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:38:58

US3512063

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:38:58

US3512063

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:38:58

US3512063

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4)	13 Aug 2020 20:38:58
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	13 Aug 2020 20:38:58

US3512063

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2004'	System	13 Aug 2020 20:38:58

US3512063

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:38:58

US3512063

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:38:58

US3512063

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Overweight, LLT: Overweight - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:41:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:41:10
Data point term sent to Coder	System	13 Aug 2020 20:40:08
User entered 'overweight'	Brenda Anderson (b) (4)	13 Aug 2020 20:39:25

US3512063

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:39:25

US3512063

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:39:25

US3512063

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:39:25

US3512063

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:39:25

US3512063

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:39:25

US3512063

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	13 Aug 2020 20:39:25

US3512063

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2005'	System	13 Aug 2020 20:39:25

US3512063

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:39:25

US3512063

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:39:25

US3512063

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:42:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:42:13
Data point term sent to Coder	System	13 Aug 2020 20:41:12
User entered 'edema lower extremities'	Brenda Anderson (b) (4)	13 Aug 2020 20:40:27

US3512063

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:40:27

US3512063

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:40:27

US3512063

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:40:27

US3512063

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:40:27

US3512063

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:40:27

US3512063

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	13 Aug 2020 20:40:27

US3512063

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2000'	System	13 Aug 2020 20:40:27

US3512063

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:40:27

US3512063

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:40:27

US3512063

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth infection, LLT: Tooth infection - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:44:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:44:09
Data point term sent to Coder	System	13 Aug 2020 20:43:17
User entered 'tooth infection'	Brenda Anderson (b) (4)	13 Aug 2020 20:42:24

US3512063

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	15 Aug 2020 17:23:48
User entered '20 Jul 2020' reason for change: Data Entry Error	Taylor Johnson (b) (4)	15 Aug 2020 17:23:48
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	
User entered empty.	System	13 Aug 2020 20:42:24
	Brenda Anderson (b) (4)	13 Aug 2020 20:42:24
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:42:24

US3512063

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 17:23:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 17:23:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 17:23:48
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 20:42:24
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:42:24

US3512063

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:42:24
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:42:24

US3512063

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	15 Aug 2020 17:23:48
User entered empty.	System	13 Aug 2020 20:42:24

US3512063

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2020'	System	15 Aug 2020 17:23:48
User entered empty.	System	13 Aug 2020 20:42:24

US3512063

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:42:24

US3512063

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:42:24

US3512063

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Smoker - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:44:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:44:07
Data point term sent to Coder	System	13 Aug 2020 20:43:20
User entered 'smoker'	Brenda Anderson (b) (4)	13 Aug 2020 20:43:06
	(b) (4)	

US3512063

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	15 Aug 2020 17:24:07
User entered 'UN UNK 1995' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 17:24:07
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 20:43:06
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:43:06

US3512063

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:43:06

US3512063

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:43:06

US3512063

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:43:06

US3512063

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:43:06

US3512063

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	15 Aug 2020 17:24:07
User entered empty.	System	13 Aug 2020 20:43:06

US3512063

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '1995'	System	15 Aug 2020 17:24:07
User entered empty.	System	13 Aug 2020 20:43:06

US3512063

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	13 Aug 2020 20:43:06

US3512063

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '2019'	System	13 Aug 2020 20:43:06

US3512063

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Toe osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:20:51
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 14:20:51
Data point term sent to Coder	System	01 Oct 2020 13:08:34
User entered 'osteoarthritis right big toe'	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 13:07:49

US3512063

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 1993'	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 13:07:49

US3512063

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 13:07:49

US3512063

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 13:07:49

US3512063

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 13:07:49

US3512063

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 13:07:49

US3512063

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 1993'	System	01 Oct 2020 13:07:49

US3512063

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '1993'	System	01 Oct 2020 13:07:49

US3512063

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:07:49

US3512063

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:07:49

US3512063

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:28:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis shoulders - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 13:09:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 13:09:48
Data point term sent to Coder	System	01 Oct 2020 13:08:33
User entered 'osteoarthritis bilateral shoulders'	Taylor Johnson (b) (4)	01 Oct 2020 13:08:12

US3512063

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'un UNK 1993'	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 13:08:12

US3512063

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 13:08:12

US3512063

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 13:08:12

US3512063

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 13:08:12

US3512063

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 13:08:12

US3512063

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Jan 1993'	System	01 Oct 2020 13:08:12

US3512063

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '1993'	System	01 Oct 2020 13:08:12

US3512063

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:08:12

US3512063

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:08:12

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	13 Aug 2020 20:48:45
	(b) (4)	

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:17'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 14:17'	System	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '63' in	Brenda Anderson (b) (4)	13 Aug 2020 20:48:45
DataPoint set to visible.	(b) (4) System	13 Aug 2020 19:03:55

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '214.8' lb	Brenda Anderson (b) (4)	13 Aug 2020 20:48:45
DataPoint set to visible.	(b) (4) System	13 Aug 2020 19:03:55

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '38.12967'	System	16 Sep 2020 23:55:44
User entered '38.1'	System	13 Aug 2020 20:48:45
DataPoint set to visible.	System	13 Aug 2020 19:03:55

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	13 Aug 2020 20:48:45
DataPoint set to visible.	System	13 Aug 2020 19:03:55

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 16:52:17
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Brenda Anderson (b) (4)	13 Aug 2020 20:48:51
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 20:48:45
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 20:48:45

US3512063

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:49:33

US3512063

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:54

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 17:33:16
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		10 Sep 2020 16:49:00
User entered '13 Aug 2020'	Brenda Anderson (b) (4)	13 Aug 2020 20:49:33
	(b) (4)	

US3512063

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:28:54

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:49:55

US3512063

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:28:54

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	13 Aug 2020 20:49:55
	(b) (4)	

US3512063

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:28:54

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:49:55

US3512063

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:28:54

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:49:55

US3512063

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:49:55

US3512063

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:28:54

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:49:55

US3512063

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:49:55

US3512063

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:28:54

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:49:55

US3512063

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:08
	(b) (4)	

US3512063

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:50:08

US3512063

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:08
	(b) (4)	

US3512063

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:08
	(b) (4)	

US3512063

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

Was FSH sample collected?

Audit	User	Time (GMT)
User closed query 'Per CDM: As per the CCG Guidelines Page number 24, Was FSH sample collected: Select Yes OR No, Update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 06:05:38
Query 'Per CDM: As per the CCG Guidelines Page number 24, Was FSH sample collected: Select Yes OR No, Update accordingly.' answered with 'done' (Site from DM).	Brenda Anderson (b) (4)	11 Sep 2020 13:39:41
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	11 Sep 2020 13:39:33
User opened query 'Per CDM: As per the CCG Guidelines Page number 24, Was FSH sample collected: Select Yes OR No, Update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:54:39
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:50:08

US3512063

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:50:08

US3512063

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:50:08

US3512063

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:50:08

US3512063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:51
	(b) (4)	

US3512063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:50:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:51
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:51
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:51
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:51
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:50:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:51
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:51
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:51
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:50:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:51
	(b) (4)	

US3512063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:50:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:51
	(b) (4)	

US3512063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:50:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4)	13 Aug 2020 20:50:51
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '1'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:50:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:50:51

US3512063

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:54

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:50:51

US3512063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	13 Aug 2020 20:51:29
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Brenda Anderson (b) (4)	13 Aug 2020 20:51:29
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:51:29

US3512063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	13 Aug 2020 20:51:29

US3512063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:54

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	13 Aug 2020 18:24:41

US3512063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:54

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:15:34
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:15:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 18:24:41
User entered '103957' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 18:24:41

US3512063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:54

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) 	13 Aug 2020 18:24:41

US3512063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:54

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	13 Aug 2020 20:52:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:54

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:52:08

US3512063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:54

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:52:08

US3512063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:54

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	13 Aug 2020 20:52:08
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:54

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:52:08

US3512063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:54

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 03:04:03
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'Completed' (Site from DM).	Allison Crain (b) (4)	04 Nov 2020 16:41:56
User entered 'No (N)'	Allison Crain (b) (4)	04 Nov 2020 16:41:52
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:56:28
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:05:23

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:54

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:54

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:54

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:54

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	13 Aug 2020 20:54:18
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:45'	Brenda Anderson (b) (4)	13 Aug 2020 20:54:18
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 13:45'	System	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	13 Aug 2020 20:54:18
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '88'	Brenda Anderson (b) (4)	13 Aug 2020 20:54:18
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '110'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:54

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:54

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	13 Aug 2020 20:54:18
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:15:30
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minutes per protocol' (Site from System).	Taylor Johnson (b) (4) (b) (4)	14 Aug 2020 01:17:26
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	13 Aug 2020 20:54:18
User entered '15:18'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 15:18'	System	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	Brenda Anderson (b) (4)	13 Aug 2020 20:54:18
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:54:18
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '125'	Brenda Anderson (b) (4)	13 Aug 2020 20:54:18
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	Brenda Anderson (b) (4)	13 Aug 2020 20:54:18
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 20:54:18

US3512063

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:54

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	13 Aug 2020 20:54:32
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:54:32

US3512063

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User closed query 'Re-query: Since both screening and Visit 1 Day 1 was done on the same day. Please consider updating pregnancy test to "No" since you only need to enter data one time under the screening folder when 2 visits occur on the same date and rest pregnancy related data fields blank. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 05:39:00
Query 'Re-query: Since both screening and Visit 1 Day 1 was done on the same day. Please consider updating pregnancy test to "No" since you only need to enter data one time under the screening folder when 2 visits occur on the same date and rest pregnancy related data fields blank. Thank you' answered with 'done' (Site from DM).	Brenda Anderson (b) (4)	17 Sep 2020 19:47:14
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	17 Sep 2020 19:46:58
User opened query 'Re-query: Since both screening and Visit 1 Day 1 was done on the same day. Please consider updating pregnancy test to "No" since you only need to enter data one time under the screening folder when 2 visits occur on the same date and rest pregnancy related data fields blank. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 02:46:25
User closed query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 02:46:06
Query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' answered with 'If a participant is screened, enrolled, randomized, and dose on the same day Enter the following under the Screening Visit folder: Pregnancy Test (if applicable) Enter the following under Visit 1 Day 1 Folder: Pregnancy Test (if applicable) ' (Site from DM).	Brenda Anderson (b) (4)	11 Sep 2020 15:14:13

v6.020 DTW (1102)

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM). User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 06:32:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 20:54:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	13 Aug 2020 20:54:53
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 20:54:48
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:54:48

US3512063

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	17 Sep 2020 19:46:58
User entered '13 Aug 2020'	Brenda Anderson (b) (4)	13 Aug 2020 20:54:48

US3512063

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Test performed](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	17 Sep 2020 19:46:58
User entered 'Urine (URINE)'	Brenda Anderson (b) (4)	13 Aug 2020 20:54:48

US3512063

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Result](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	17 Sep 2020 19:46:58
User entered 'Negative (NEGATIVE)'	Brenda Anderson (b) (4)	13 Aug 2020 20:54:48

US3512063

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	(b) (4) 17 Sep 2020 19:46:58
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	(b) (4) 11 Sep 2020 15:13:22
User entered empty.	Brenda Anderson (b) (4)	(b) (4) 13 Aug 2020 20:54:48

US3512063

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:54:48
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:54:48
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:54:48

US3512063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:20:31

US3512063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:20:31

US3512063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:20:31

US3512063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 19:20:31

US3512063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:20:31

US3512063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:48'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:20:31

US3512063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 14:48'	System	13 Aug 2020 19:20:31

US3512063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Taylor Johnson (b) (4) (b) (4)	13 Aug 2020 19:20:31

US3512063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	13 Aug 2020 19:20:31

US3512063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 19:20:31

US3512063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:55:15

US3512063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:55:15

US3512063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:06'	Brenda Anderson (b) (4)	13 Aug 2020 20:55:15
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 14:06'	System	13 Aug 2020 20:55:15

US3512063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:55:33

US3512063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:54

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Anderson (b) (4)	13 Aug 2020 20:55:33

US3512063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:55:33

US3512063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:17'	Brenda Anderson (b) (4)	13 Aug 2020 20:55:33
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 14:17'	System	13 Aug 2020 20:55:33

US3512063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:54

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Anderson (b) (4)	13 Aug 2020 20:55:33

US3512063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:55:33

US3512063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 20:55:33
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:55:33

US3512063

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	13 Aug 2020 20:55:41
	(b) (4)	

US3512063

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 20:55:41

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:21:07', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'a0777bc3-b4ff-4c62-9f61-e463cb7be55a'	System	13 Aug 2020 19:21:35
User entered 'Yes (Y)'	System	13 Aug 2020 19:21:35

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:21:20', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'a0777bc3-b4ff-4c62-9f61-e463cb7be55a'	System	13 Aug 2020 19:21:35
User entered '97.6'	System	13 Aug 2020 19:21:35

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:21:26', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'a0777bc3-b4ff-4c62-9f61-e463cb7be55a'	System	13 Aug 2020 19:21:35
User entered 'No (N)'	System	13 Aug 2020 19:21:35

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:21:31', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'a0777bc3-b4ff-4c62-9f61-e463cb7be55a'	System	13 Aug 2020 19:21:35
User entered '13 Aug 2020 15:21'	System	13 Aug 2020 19:21:35

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 15:08'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 17:38'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:33:26', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'c29e5cf0-bc96-4051-ad48-8b697b2f61b0'	System	14 Aug 2020 15:33:47
User entered 'Yes (Y)'	System	14 Aug 2020 15:33:47

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:33:32', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'c29e5cf0-bc96-4051-ad48-8b697b2f61b0'	System	14 Aug 2020 15:33:47
User entered '98.2'	System	14 Aug 2020 15:33:47

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:33:38', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'c29e5cf0-bc96-4051-ad48-8b697b2f61b0'	System	14 Aug 2020 15:33:47
User entered 'No (N)'	System	14 Aug 2020 15:33:47

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:33:46', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'c29e5cf0-bc96-4051-ad48-8b697b2f61b0'	System	14 Aug 2020 15:33:47
User entered '14 Aug 2020 11:33'	System	14 Aug 2020 15:33:47

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 18:33'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 2'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:00:57', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'b4f245d1-8eea-414b-a720-ad8622e1626d'	System	15 Aug 2020 15:01:16
User entered 'Yes (Y)'	System	15 Aug 2020 15:01:16

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:01:03', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'b4f245d1-8eea-414b-a720-ad8622e1626d'	System	15 Aug 2020 15:01:16
User entered '98.2'	System	15 Aug 2020 15:01:16

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:01:06', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'b4f245d1-8eea-414b-a720-ad8622e1626d'	System	15 Aug 2020 15:01:16
User entered 'No (N)'	System	15 Aug 2020 15:01:16

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:01:14', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'b4f245d1-8eea-414b-a720-ad8622e1626d'	System	15 Aug 2020 15:01:16
User entered '15 Aug 2020 11:01'	System	15 Aug 2020 15:01:16

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 3'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:28:31', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '0145b503-119a-4669-a952-286f857c804c'	System	16 Aug 2020 15:28:59
User entered 'Yes (Y)'	System	16 Aug 2020 15:28:59

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:28:39', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '0145b503-119a-4669-a952-286f857c804c'	System	16 Aug 2020 15:28:59
User entered '97.2'	System	16 Aug 2020 15:28:59

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:28:48', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '0145b503-119a-4669-a952-286f857c804c'	System	16 Aug 2020 15:28:59
User entered 'No (N)'	System	16 Aug 2020 15:28:59

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:28:57', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '0145b503-119a-4669-a952-286f857c804c'	System	16 Aug 2020 15:28:59
User entered '16 Aug 2020 11:28'	System	16 Aug 2020 15:28:59

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 4'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 5'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:18:19', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '78974310-76bc-4d8b-9ea1-f7aede69318a'	System	17 Aug 2020 16:19:22
User entered 'Yes (Y)'	System	17 Aug 2020 16:19:22

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:19:11', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '78974310-76bc-4d8b-9ea1-f7aede69318a'	System	17 Aug 2020 16:19:22
User entered '98.8'	System	17 Aug 2020 16:19:22

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:19:15', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '78974310-76bc-4d8b-9ea1-f7aede69318a'	System	17 Aug 2020 16:19:22
User entered 'No (N)'	System	17 Aug 2020 16:19:22

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:19:19', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '78974310-76bc-4d8b-9ea1-f7aede69318a'	System	17 Aug 2020 16:19:22
User entered '17 Aug 2020 12:19'	System	17 Aug 2020 16:19:22

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 6'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:16:02', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '353351ab-b1f3-4ed9-a14e-40b83b480733'	System	19 Aug 2020 14:16:44
User entered 'Yes (Y)'	System	19 Aug 2020 14:16:44

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:16:30', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '353351ab-b1f3-4ed9-a14e-40b83b480733'	System	19 Aug 2020 14:16:44
User entered '97.6'	System	19 Aug 2020 14:16:44

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:16:38', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '353351ab-b1f3-4ed9-a14e-40b83b480733'	System	19 Aug 2020 14:16:44
User entered 'No (N)'	System	19 Aug 2020 14:16:44

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:16:41', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '353351ab-b1f3-4ed9-a14e-40b83b480733'	System	19 Aug 2020 14:16:44
User entered '19 Aug 2020 10:16'	System	19 Aug 2020 14:16:44

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 7'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:10:13', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'dedfefac-9d25-46c0-b678-49047ae9e4ab'	System	20 Aug 2020 13:10:30
User entered 'Yes (Y)'	System	20 Aug 2020 13:10:30

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:10:18', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'dedfefac-9d25-46c0-b678-49047ae9e4ab'	System	20 Aug 2020 13:10:30
User entered '97.6'	System	20 Aug 2020 13:10:30

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:10:21', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'dedfefac-9d25-46c0-b678-49047ae9e4ab'	System	20 Aug 2020 13:10:30
User entered 'No (N)'	System	20 Aug 2020 13:10:30

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:10:26', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'dedfefac-9d25-46c0-b678-49047ae9e4ab'	System	20 Aug 2020 13:10:30
User entered '20 Aug 2020 09:10'	System	20 Aug 2020 13:10:30

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:22:00', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '4252e585-5973-476c-b92e-7d8616676cfb'	System	13 Aug 2020 19:22:39
User entered 'None (1)'	System	13 Aug 2020 19:22:39

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:22:08', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '4252e585-5973-476c-b92e-7d8616676cfb'	System	13 Aug 2020 19:22:39
User entered 'No (N)'	System	13 Aug 2020 19:22:39

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:22:19', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '4252e585-5973-476c-b92e-7d8616676cfb'	System	13 Aug 2020 19:22:39
User entered 'No (N)'	System	13 Aug 2020 19:22:39

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:22:32', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '4252e585-5973-476c-b92e-7d8616676cfb'	System	13 Aug 2020 19:22:39
User entered 'None (1)'	System	13 Aug 2020 19:22:39

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:22:37', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '4252e585-5973-476c-b92e-7d8616676cfb'	System	13 Aug 2020 19:22:39
User entered '13 Aug 2020 15:22'	System	13 Aug 2020 19:22:39

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 15:08'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 17:38'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:33:52', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'd577bac5-c74d-4efe-be5a-36420ee40a7f'	System	14 Aug 2020 15:34:29
User entered 'None (1)'	System	14 Aug 2020 15:34:29

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:33:55', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'd577bac5-c74d-4efe-be5a-36420ee40a7f'	System	14 Aug 2020 15:34:29
User entered 'No (N)'	System	14 Aug 2020 15:34:29

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:34:06', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'd577bac5-c74d-4efe-be5a-36420ee40a7f'	System	14 Aug 2020 15:34:29
User entered 'No (N)'	System	14 Aug 2020 15:34:29

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:34:17', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'd577bac5-c74d-4efe-be5a-36420ee40a7f'	System	14 Aug 2020 15:34:29
User entered 'None (1)'	System	14 Aug 2020 15:34:29

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:34:23', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'd577bac5-c74d-4efe-be5a-36420ee40a7f' User entered '14 Aug 2020 11:34'	System	14 Aug 2020 15:34:29
	System	14 Aug 2020 15:34:29

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 18:33'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 2'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:01:26', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '165a5aaf-5ffd-44b8-b78a-d6e8837af51b'	System	15 Aug 2020 15:01:54
User entered 'None (1)'	System	15 Aug 2020 15:01:54

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:01:29', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '165a5aaf-5ffd-44b8-b78a-d6e8837af51b'	System	15 Aug 2020 15:01:54
User entered 'No (N)'	System	15 Aug 2020 15:01:54

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:01:31', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '165a5aaf-5ffd-44b8-b78a-d6e8837af51b'	System	15 Aug 2020 15:01:54
User entered 'No (N)'	System	15 Aug 2020 15:01:54

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:01:47', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '165a5aaf-5ffd-44b8-b78a-d6e8837af51b'	System	15 Aug 2020 15:01:54
User entered 'None (1)'	System	15 Aug 2020 15:01:54

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:01:52', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '165a5aaf-5ffd-44b8-b78a-d6e8837af51b'	System	15 Aug 2020 15:01:54
User entered '15 Aug 2020 11:01'	System	15 Aug 2020 15:01:54

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 3'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:29:04', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '1a4e827d-901a-4de2-bbba-3890d7c67989'	System	16 Aug 2020 15:29:38
User entered 'None (1)'	System	16 Aug 2020 15:29:38

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:29:07', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '1a4e827d-901a-4de2-bbba-3890d7c67989'	System	16 Aug 2020 15:29:38
User entered 'No (N)'	System	16 Aug 2020 15:29:38

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:29:17', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '1a4e827d-901a-4de2-bbba-3890d7c67989'	System	16 Aug 2020 15:29:38
User entered 'No (N)'	System	16 Aug 2020 15:29:38

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:29:28', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '1a4e827d-901a-4de2-bbba-3890d7c67989'	System	16 Aug 2020 15:29:38
User entered 'None (1)'	System	16 Aug 2020 15:29:38

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:29:34', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '1a4e827d-901a-4de2-bbba-3890d7c67989'	System	16 Aug 2020 15:29:38
User entered '16 Aug 2020 11:29'	System	16 Aug 2020 15:29:38

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 4'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 5'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:19:23', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '8696dde6-f8ea-4fa6-a7f9-6fa9089e84d9'	System	17 Aug 2020 16:19:55
User entered 'None (1)'	System	17 Aug 2020 16:19:55

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:19:27', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '8696dde6-f8ea-4fa6-a7f9-6fa9089e84d9'	System	17 Aug 2020 16:19:55
User entered 'No (N)'	System	17 Aug 2020 16:19:55

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:19:35', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '8696dde6-f8ea-4fa6-a7f9-6fa9089e84d9'	System	17 Aug 2020 16:19:55
User entered 'No (N)'	System	17 Aug 2020 16:19:55

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:19:47', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '8696dde6-f8ea-4fa6-a7f9-6fa9089e84d9'	System	17 Aug 2020 16:19:55
User entered 'None (1)'	System	17 Aug 2020 16:19:55

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:19:51', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '8696dde6-f8ea-4fa6-a7f9-6fa9089e84d9'	System	17 Aug 2020 16:19:55
User entered '17 Aug 2020 12:19'	System	17 Aug 2020 16:19:55

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 6'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:16:46', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'cd25ece3-db76-49a2-905b-580f00b6d9df'	System	19 Aug 2020 14:17:07
User entered 'None (1)'	System	19 Aug 2020 14:17:07

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:16:49', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'cd25ece3-db76-49a2-905b-580f00b6d9df'	System	19 Aug 2020 14:17:07
User entered 'No (N)'	System	19 Aug 2020 14:17:07

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:16:51', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'cd25ece3-db76-49a2-905b-580f00b6d9df'	System	19 Aug 2020 14:17:07
User entered 'No (N)'	System	19 Aug 2020 14:17:07

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:17:00', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'cd25ece3-db76-49a2-905b-580f00b6d9df'	System	19 Aug 2020 14:17:07
User entered 'None (1)'	System	19 Aug 2020 14:17:07

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:17:02', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'cd25ece3-db76-49a2-905b-580f00b6d9df'	System	19 Aug 2020 14:17:07
User entered '19 Aug 2020 10:17'	System	19 Aug 2020 14:17:07

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 7'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:10:39', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '4218d53c-f438-4dec-8d65-531682376989'	System	20 Aug 2020 13:11:03
User entered 'None (1)'	System	20 Aug 2020 13:11:03

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:10:47', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '4218d53c-f438-4dec-8d65-531682376989'	System	20 Aug 2020 13:11:03
User entered 'No (N)'	System	20 Aug 2020 13:11:03

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:10:49', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '4218d53c-f438-4dec-8d65-531682376989'	System	20 Aug 2020 13:11:03
User entered 'No (N)'	System	20 Aug 2020 13:11:03

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:10:55', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '4218d53c-f438-4dec-8d65-531682376989'	System	20 Aug 2020 13:11:03
User entered 'None (1)'	System	20 Aug 2020 13:11:03

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:10:58', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '4218d53c-f438-4dec-8d65-531682376989'	System	20 Aug 2020 13:11:03
User entered '20 Aug 2020 09:10'	System	20 Aug 2020 13:11:03

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:22:46', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'c83372ee-8d26-4699-a4e2-45466621f2e8'	System	13 Aug 2020 19:23:41
User entered 'None (0)'	System	13 Aug 2020 19:23:41

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:22:50', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'c83372ee-8d26-4699-a4e2-45466621f2e8'	System	13 Aug 2020 19:23:41
User entered 'None (0)'	System	13 Aug 2020 19:23:41

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:22:52', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'c83372ee-8d26-4699-a4e2-45466621f2e8' User entered 'None (0)'	System	13 Aug 2020 19:23:41
	System	13 Aug 2020 19:23:41

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:22:54', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'c83372ee-8d26-4699-a4e2-45466621f2e8' User entered 'None (0)'	System	13 Aug 2020 19:23:41
	System	13 Aug 2020 19:23:41

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:22:57', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'c83372ee-8d26-4699-a4e2-45466621f2e8'	System	13 Aug 2020 19:23:41
User entered 'None (0)'	System	13 Aug 2020 19:23:41

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:23:00', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'c83372ee-8d26-4699-a4e2-45466621f2e8'	System	13 Aug 2020 19:23:41
User entered 'None (0)'	System	13 Aug 2020 19:23:41

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:23:33', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'c83372ee-8d26-4699-a4e2-45466621f2e8'	System	13 Aug 2020 19:23:41
User entered 'No (N)'	System	13 Aug 2020 19:23:41

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-13T15:23:39', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'c83372ee-8d26-4699-a4e2-45466621f2e8'	System	13 Aug 2020 19:23:41
User entered '13 Aug 2020 15:23'	System	13 Aug 2020 19:23:41

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 15:08'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 17:38'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:34:30', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '41526fdb-523c-43bc-8f01-624f393e174c'	System	14 Aug 2020 15:34:57
User entered 'None (0)'	System	14 Aug 2020 15:34:57

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:34:32', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '41526fdb-523c-43bc-8f01-624f393e174c'	System	14 Aug 2020 15:34:57
User entered 'None (0)'	System	14 Aug 2020 15:34:57

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:34:35', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '41526fdb-523c-43bc-8f01-624f393e174c'	System	14 Aug 2020 15:34:57
User entered 'None (0)'	System	14 Aug 2020 15:34:57

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:34:37', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '41526fdb-523c-43bc-8f01-624f393e174c'	System	14 Aug 2020 15:34:57
User entered 'None (0)'	System	14 Aug 2020 15:34:57

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:34:40', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '41526fdb-523c-43bc-8f01-624f393e174c'	System	14 Aug 2020 15:34:57
User entered 'None (0)'	System	14 Aug 2020 15:34:57

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:34:41', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '41526fdb-523c-43bc-8f01-624f393e174c'	System	14 Aug 2020 15:34:57
User entered 'None (0)'	System	14 Aug 2020 15:34:57

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:34:47', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '41526fdb-523c-43bc-8f01-624f393e174c'	System	14 Aug 2020 15:34:57
User entered 'No (N)'	System	14 Aug 2020 15:34:57

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-14T11:34:53', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '41526fdb-523c-43bc-8f01-624f393e174c'	System	14 Aug 2020 15:34:57
User entered '14 Aug 2020 11:34'	System	14 Aug 2020 15:34:57

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 18:33'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 2'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:01:56', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '1e2935a0-a324-40c4-9770-f433b8de00fd'	System	15 Aug 2020 15:02:18
User entered 'None (0)'	System	15 Aug 2020 15:02:18

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:01:59', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '1e2935a0-a324-40c4-9770-f433b8de00fd'	System	15 Aug 2020 15:02:18
User entered 'None (0)'	System	15 Aug 2020 15:02:18

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:02:01', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '1e2935a0-a324-40c4-9770-f433b8de00fd'	System	15 Aug 2020 15:02:18
User entered 'None (0)'	System	15 Aug 2020 15:02:18

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:02:04', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '1e2935a0-a324-40c4-9770-f433b8de00fd' User entered 'None (0)'	System	15 Aug 2020 15:02:18
	System	15 Aug 2020 15:02:18

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:02:07', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '1e2935a0-a324-40c4-9770-f433b8de00fd'	System	15 Aug 2020 15:02:18
User entered 'None (0)'	System	15 Aug 2020 15:02:18

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:02:09', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '1e2935a0-a324-40c4-9770-f433b8de00fd'	System	15 Aug 2020 15:02:18
User entered 'None (0)'	System	15 Aug 2020 15:02:18

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:02:12', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '1e2935a0-a324-40c4-9770-f433b8de00fd'	System	15 Aug 2020 15:02:18
User entered 'No (N)'	System	15 Aug 2020 15:02:18

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-15T11:02:16', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '1e2935a0-a324-40c4-9770-f433b8de00fd'	System	15 Aug 2020 15:02:18
User entered '15 Aug 2020 11:02'	System	15 Aug 2020 15:02:18

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 3'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:29:41', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '6f243487-192f-4576-8aad-5758f9823b9f'	System	16 Aug 2020 15:30:42
User entered 'None (0)'	System	16 Aug 2020 15:30:42

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:29:43', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '6f243487-192f-4576-8aad-5758f9823b9f'	System	16 Aug 2020 15:30:42
User entered 'None (0)'	System	16 Aug 2020 15:30:42

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:29:45', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '6f243487-192f-4576-8aad-5758f9823b9f'	System	16 Aug 2020 15:30:42
User entered 'None (0)'	System	16 Aug 2020 15:30:42

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:29:48', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '6f243487-192f-4576-8aad-5758f9823b9f'	System	16 Aug 2020 15:30:42
User entered 'None (0)'	System	16 Aug 2020 15:30:42

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:29:50', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '6f243487-192f-4576-8aad-5758f9823b9f'	System	16 Aug 2020 15:30:42
User entered 'None (0)'	System	16 Aug 2020 15:30:42

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:29:54', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '6f243487-192f-4576-8aad-5758f9823b9f'	System	16 Aug 2020 15:30:42
User entered 'None (0)'	System	16 Aug 2020 15:30:42

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:30:30', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '6f243487-192f-4576-8aad-5758f9823b9f'	System	16 Aug 2020 15:30:42
User entered 'No (N)'	System	16 Aug 2020 15:30:42

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-16T11:30:39', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '6f243487-192f-4576-8aad-5758f9823b9f'	System	16 Aug 2020 15:30:42
User entered '16 Aug 2020 11:30'	System	16 Aug 2020 15:30:42

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 4'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 5'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:19:55', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'fc482db4-3184-4960-adc3-24521a922789'	System	17 Aug 2020 16:20:17
User entered 'None (0)'	System	17 Aug 2020 16:20:17

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:19:57', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'fc482db4-3184-4960-adc3-24521a922789'	System	17 Aug 2020 16:20:17
User entered 'None (0)'	System	17 Aug 2020 16:20:17

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:19:59', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'fc482db4-3184-4960-adc3-24521a922789'	System	17 Aug 2020 16:20:17
User entered 'None (0)'	System	17 Aug 2020 16:20:17

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:20:00', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'fc482db4-3184-4960-adc3-24521a922789'	System	17 Aug 2020 16:20:17
User entered 'None (0)'	System	17 Aug 2020 16:20:17

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:20:02', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'fc482db4-3184-4960-adc3-24521a922789'	System	17 Aug 2020 16:20:17
User entered 'None (0)'	System	17 Aug 2020 16:20:17

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:20:04', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'fc482db4-3184-4960-adc3-24521a922789'	System	17 Aug 2020 16:20:17
User entered 'None (0)'	System	17 Aug 2020 16:20:17

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:20:07', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'fc482db4-3184-4960-adc3-24521a922789'	System	17 Aug 2020 16:20:17
User entered 'No (N)'	System	17 Aug 2020 16:20:17

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-17T12:20:10', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'fc482db4-3184-4960-adc3-24521a922789'	System	17 Aug 2020 16:20:17
User entered '17 Aug 2020 12:20'	System	17 Aug 2020 16:20:17

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 6'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:17:06', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'b0dbb17b-ca78-4b1a-ae24-00f93ccd160b'	System	19 Aug 2020 14:17:24
User entered 'None (0)'	System	19 Aug 2020 14:17:24

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:17:08', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'b0dbb17b-ca78-4b1a-ae24-00f93ccd160b'	System	19 Aug 2020 14:17:24
User entered 'None (0)'	System	19 Aug 2020 14:17:24

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:17:09', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'b0dbb17b-ca78-4b1a-ae24-00f93ccd160b'	System	19 Aug 2020 14:17:24
User entered 'None (0)'	System	19 Aug 2020 14:17:24

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:17:11', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'b0dbb17b-ca78-4b1a-ae24-00f93ccd160b' User entered 'None (0)'	System	19 Aug 2020 14:17:24
	System	19 Aug 2020 14:17:24

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:17:13', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'b0dbb17b-ca78-4b1a-ae24-00f93ccd160b'	System	19 Aug 2020 14:17:24
User entered 'None (0)'	System	19 Aug 2020 14:17:24

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:17:15', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'b0dbb17b-ca78-4b1a-ae24-00f93ccd160b'	System	19 Aug 2020 14:17:24
User entered 'None (0)'	System	19 Aug 2020 14:17:24

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:17:19', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'b0dbb17b-ca78-4b1a-ae24-00f93ccd160b'	System	19 Aug 2020 14:17:24
User entered 'No (N)'	System	19 Aug 2020 14:17:24

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-19T10:17:22', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'b0dbb17b-ca78-4b1a-ae24-00f93ccd160b'	System	19 Aug 2020 14:17:24
User entered '19 Aug 2020 10:17'	System	19 Aug 2020 14:17:24

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 7'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:11:11', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'bf59f486-79c9-484d-ba6b-a8477bf33793'	System	20 Aug 2020 13:36:26
User entered 'None (0)'	System	20 Aug 2020 13:36:26

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:11:14', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'bf59f486-79c9-484d-ba6b-a8477bf33793'	System	20 Aug 2020 13:36:26
User entered 'None (0)'	System	20 Aug 2020 13:36:26

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:35:25', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'bf59f486-79c9-484d-ba6b-a8477bf33793'	System	20 Aug 2020 13:36:26
User entered 'None (0)'	System	20 Aug 2020 13:36:26

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:35:38', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'bf59f486-79c9-484d-ba6b-a8477bf33793'	System	20 Aug 2020 13:36:26
User entered 'None (0)'	System	20 Aug 2020 13:36:26

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:36:05', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'bf59f486-79c9-484d-ba6b-a8477bf33793'	System	20 Aug 2020 13:36:26
User entered 'None (0)'	System	20 Aug 2020 13:36:26

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:36:15', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'bf59f486-79c9-484d-ba6b-a8477bf33793'	System	20 Aug 2020 13:36:26
User entered 'None (0)'	System	20 Aug 2020 13:36:26

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:54

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 (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:36:18', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'bf59f486-79c9-484d-ba6b-a8477bf33793'	System	20 Aug 2020 13:36:26
User entered 'No (N)'	System	20 Aug 2020 13:36:26

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-08-20T09:36:22', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'bf59f486-79c9-484d-ba6b-a8477bf33793'	System	20 Aug 2020 13:36:26
User entered '20 Aug 2020 09:36'	System	20 Aug 2020 13:36:26

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 19:20:31

US3512063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	20 Aug 2020 16:08:00

US3512063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Sheldon Warren (b) (4) (b) (4)	20 Aug 2020 16:08:00

US3512063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	20 Aug 2020 16:08:00

US3512063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	20 Aug 2020 16:08:00

US3512063

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	20 Aug 2020 16:08:06

US3512063

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:08:06

US3512063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	28 Aug 2020 17:05:09

US3512063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Sheldon Warren (b) (4) (b) (4)	28 Aug 2020 17:05:09

US3512063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	28 Aug 2020 17:05:09

US3512063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	28 Aug 2020 17:05:09

US3512063

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	28 Aug 2020 17:05:15

US3512063

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:05:15

US3512063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	10 Sep 2020 16:32:09
	(b) (4)	

US3512063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020'	Brenda Anderson (b) (4)	10 Sep 2020 16:32:09
	(b) (4)	

US3512063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Brenda Anderson (b) (4)	10 Sep 2020 16:32:09

US3512063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:32:09

US3512063

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:32:19

US3512063

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:32:19

US3512063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	10 Sep 2020 16:49:00
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Brenda Anderson (b) (4)	10 Sep 2020 16:49:00
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:49:00

US3512063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	10 Sep 2020 16:49:00

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4)	10 Sep 2020 16:52:47
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	10 Sep 2020 16:52:47
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:11'	Brenda Anderson (b) (4)	10 Sep 2020 16:52:47
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:11'	System	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.2' F	Brenda Anderson (b) (4)	10 Sep 2020 16:52:47
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	10 Sep 2020 16:52:47
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '100'	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '20'	Brenda Anderson (b) (4)	10 Sep 2020 16:52:47
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '112'	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '86'	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4)	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	10 Sep 2020 16:52:47
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

Pulse (xxx)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	10 Sep 2020 16:52:47
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	10 Sep 2020 16:52:47
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	10 Sep 2020 16:52:47
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	10 Sep 2020 16:52:47
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:52:47

US3512063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:54

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	10 Sep 2020 16:53:18
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Brenda Anderson (b) (4)	10 Sep 2020 16:53:18
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	10 Sep 2020 16:53:35
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:53:35

US3512063

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Brenda Anderson (b) (4)	10 Sep 2020 16:53:35
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Brenda Anderson (b) (4)	10 Sep 2020 16:53:35
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:53:35

US3512063

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	10 Sep 2020 16:53:35
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	10 Sep 2020 16:53:35
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:53:35

US3512063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:54:02

US3512063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

If No, reason not given

Audit	User	Time (GMT)
User closed query 'Per CDM: Please complete the Covid-19 Assessment, Adverse Event page and dosing discontinuation page for the Covid-19 diagnosis.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:43:13
Query 'Per CDM: Please complete the Covid-19 Assessment, Adverse Event page and dosing discontinuation page for the Covid-19 diagnosis.' answered with 'per monitor do not complete AE page.' (Site from DM).	Brenda Anderson (b) (4)	14 Oct 2020 11:30:41
User opened query 'Per CDM: Please complete the Covid-19 Assessment, Adverse Event page and dosing discontinuation page for the Covid-19 diagnosis.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 07:05:44
User entered 'Confirmed COVID-19 (COVID)'	Brenda Anderson (b) (4)	10 Sep 2020 16:54:02

US3512063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:54:02

US3512063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:54:02

US3512063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	10 Sep 2020 16:54:02
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	10 Sep 2020 16:54:02
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:54:02

US3512063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:54:02

US3512063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:54:02

US3512063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:54

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:54:02

US3512063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:55:16

US3512063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 12:33:40
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Do to lack of supplies at site, unscheduled kit was used for this scheduled visit.' (Site from DM).	Allison Crain (b) (4)	23 Oct 2020 15:54:20
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:19:38
User entered '10 Sep 2020'	Brenda Anderson (b) (4)	10 Sep 2020 16:55:16

US3512063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:27' reason for change: Data Entry Error	Brenda Anderson (b) (4)	10 Sep 2020 16:55:45
User entered '10:27'	Brenda Anderson (b) (4)	10 Sep 2020 16:55:16

US3512063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:27'	System	10 Sep 2020 16:55:45
User entered '10 Sep 2020 10:27'	System	10 Sep 2020 16:55:16

US3512063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 10Sep2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:24:21
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 10Sep2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'Due to lack of supplies on site, UNSCHEDULED lab kits were used for the Visit 2 Day 29 labs. This was approved by monitor and are not two separate visits.' (Site from DM).	Allison Crain (b) (4)	21 Oct 2020 12:33:45
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 10Sep2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:19:39
User entered '10 Sep 2020'	Brenda Anderson (b) (4)	10 Sep 2020 16:55:34

US3512063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:54

[Lab Test](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 10Sep2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:03:51
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 10Sep2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 12:10:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Anderson (b) (4)	10 Sep 2020 16:55:34

US3512063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	10 Sep 2020 16:55:34
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:18'	Brenda Anderson (b) (4)	10 Sep 2020 16:55:34
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:18'	System	10 Sep 2020 16:55:34

US3512063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:54

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Anderson (b) (4)	10 Sep 2020 16:55:34

US3512063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 16:55:34

US3512063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	10 Sep 2020 16:55:34
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:55:34

US3512063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	10 Sep 2020 16:56:07
	(b) (4)	

US3512063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:56:07

US3512063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 12:34:25

US3512063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 12:34:25

US3512063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 12:34:25

US3512063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 12:34:25

US3512063

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 12:34:32

US3512063

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 12:34:32

US3512063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	24 Sep 2020 19:53:45

US3512063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Taylor Johnson (b) (4) (b) (4)	24 Sep 2020 19:53:45

US3512063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Taylor Johnson (b) (4) (b) (4)	24 Sep 2020 19:53:45

US3512063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	24 Sep 2020 19:53:45

US3512063

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	24 Sep 2020 19:53:50

US3512063

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 19:53:50

US3512063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 16:12:28

US3512063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020'	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 16:12:28

US3512063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 16:12:28

US3512063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 16:12:28

US3512063

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 16:12:34

US3512063

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 16:12:34

US3512063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	14 Oct 2020 11:33:23
	(b) (4)	

US3512063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Brenda Anderson (b) (4)	14 Oct 2020 11:33:23
	(b) (4)	

US3512063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4) (b) (4)	14 Oct 2020 11:33:23

US3512063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	14 Oct 2020 11:33:23

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	14 Oct 2020 11:34:15
	(b) (4)	

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Brenda Anderson (b) (4) (b) (4)	14 Oct 2020 11:34:15

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:26'	Brenda Anderson (b) (4)	14 Oct 2020 11:34:15
	(b) (4)	

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Oct 2020 11:26'	System	14 Oct 2020 11:34:15

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Oct 2020 11:34:25
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	14 Oct 2020 11:34:25
User entered '98.2' F reason for change: Data Entry Error	Brenda Anderson (b) (4)	14 Oct 2020 11:34:25
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Oct 2020 11:34:15
User entered '98.2' C	Brenda Anderson (b) (4)	14 Oct 2020 11:34:15

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	14 Oct 2020 11:34:15
	(b) (4)	

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	14 Oct 2020 11:34:15
	(b) (4)	

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '75'	Brenda Anderson (b) (4)	14 Oct 2020 11:34:15
	(b) (4)	

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Oct 2020 11:34:15

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '12'	Brenda Anderson (b) (4)	14 Oct 2020 11:34:15
	(b) (4)	

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Oct 2020 11:34:15

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '117'	Brenda Anderson (b) (4)	14 Oct 2020 11:34:15
	(b) (4)	

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Oct 2020 11:34:15

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '77'	Brenda Anderson (b) (4)	14 Oct 2020 11:34:15
	(b) (4)	

US3512063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Oct 2020 11:34:15

US3512063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	14 Oct 2020 11:34:40
	(b) (4)	

US3512063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	14 Oct 2020 11:34:40

US3512063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	14 Oct 2020 11:35:05

US3512063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Brenda Anderson (b) (4) (b) (4)	14 Oct 2020 11:35:05

US3512063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:35'	Brenda Anderson (b) (4) (b) (4)	14 Oct 2020 11:35:05

US3512063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Oct 2020 11:35'	System	14 Oct 2020 11:35:05

US3512063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	14 Oct 2020 11:35:09

US3512063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 11:35:09

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 64'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-10-16T07:40:59', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '59c29a88-33e6-46bd-a81f-38a567468ca0'	System	16 Oct 2020 11:41:16
User entered 'No (N)'	System	16 Oct 2020 11:41:16

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-10-16T07:41:06', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '59c29a88-33e6-46bd-a81f-38a567468ca0'	System	16 Oct 2020 11:41:16
User entered 'No (N)'	System	16 Oct 2020 11:41:16

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-10-16T07:41:12', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '59c29a88-33e6-46bd-a81f-38a567468ca0' User entered '16 Oct 2020 07:41:12'	System	16 Oct 2020 11:41:16
	System	16 Oct 2020 11:41:16

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 71'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-10-20T01:22:18', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'a21ae7fd-6d40-4615-8076-358f49f14139'	System	20 Oct 2020 05:22:30
User entered 'No (N)'	System	20 Oct 2020 05:22:30

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-10-20T01:22:21', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'a21ae7fd-6d40-4615-8076-358f49f14139'	System	20 Oct 2020 05:22:30
User entered 'No (N)'	System	20 Oct 2020 05:22:30

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-10-20T01:22:27', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'a21ae7fd-6d40-4615-8076-358f49f14139' User entered '20 Oct 2020 01:22:27'	System	20 Oct 2020 05:22:30
	System	20 Oct 2020 05:22:30

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 78'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-10-27T05:40:51', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '00a61637-7d95-4adc-917a-ce9687b7194c' User entered 'No (N)'	System	27 Oct 2020 09:41:07
	System	27 Oct 2020 09:41:07

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-10-27T05:40:56', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '00a61637-7d95-4adc-917a-ce9687b7194c'	System	27 Oct 2020 09:41:07
User entered 'No (N)'	System	27 Oct 2020 09:41:07

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-10-27T05:41:03', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '00a61637-7d95-4adc-917a-ce9687b7194c' User entered '27 Oct 2020 05:41:03'	System	27 Oct 2020 09:41:07
	System	27 Oct 2020 09:41:07

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 92'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-11-10T03:21:26', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '343f44f8-ced5-4cc8-8b39-d916e55e15ed'	System	10 Nov 2020 08:21:36
User entered 'No (N)'	System	10 Nov 2020 08:21:36

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-11-10T03:21:29', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '343f44f8-ced5-4cc8-8b39-d916e55e15ed'	System	10 Nov 2020 08:21:36
User entered 'No (N)'	System	10 Nov 2020 08:21:36

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-11-10T03:21:33', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '343f44f8-ced5-4cc8-8b39-d916e55e15ed' User entered '10 Nov 2020 03:21:33'	System	10 Nov 2020 08:21:36
	System	10 Nov 2020 08:21:36

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered 'Day 99'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-11-17T03:41:49', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '173e3e1a-e92e-4796-9993-43d9d370b647'	System	17 Nov 2020 08:42:02
User entered 'No (N)'	System	17 Nov 2020 08:42:02

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-11-17T03:41:54', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '173e3e1a-e92e-4796-9993-43d9d370b647'	System	17 Nov 2020 08:42:02
User entered 'No (N)'	System	17 Nov 2020 08:42:02

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-11-17T03:41:58', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: '173e3e1a-e92e-4796-9993-43d9d370b647' User entered '17 Nov 2020 03:41:58'	System	17 Nov 2020 08:42:02
	System	17 Nov 2020 08:42:02

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 19:20:31

US3512063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 19:20:31
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 19:20:31

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '10 Oct 2020 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '14 Oct 2020 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '17 Oct 2020 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '21 Oct 2020 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '24 Oct 2020 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '28 Oct 2020 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '31 Oct 2020 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '04 Nov 2020 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '07 Nov 2020 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '11 Nov 2020 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '14 Nov 2020 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '18 Nov 2020 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-11-21T09:52:31', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'f28d7520-533b-4fbe-ba8f-da1ba8adaa8a' User entered 'No (N)'	System	21 Nov 2020 14:52:45
	System	21 Nov 2020 14:52:45

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-11-21T09:52:35', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'f28d7520-533b-4fbe-ba8f-da1ba8adaa8a'	System	21 Nov 2020 14:52:45
User entered 'No (N)'	System	21 Nov 2020 14:52:45

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FCC07E0-94AE-47F1-A8A7-954CAB35CC22)', Time: '2020-11-21T09:52:42', User OID: 'PatientReportedOutcome (US3512063)', ODM File OID: 'f28d7520-533b-4fbe-ba8f-da1ba8adaa8a' User entered '21 Nov 2020 09:52:42'	System	21 Nov 2020 14:52:45
	System	21 Nov 2020 14:52:45

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:26:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:26:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:26:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:26:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:26:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:26:04

US3512063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:26:04
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:26:04

US3512063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	07 Nov 2020 19:15:49

US3512063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '7 Nov 2020'	Sheldon Warren (b) (4) (b) (4)	07 Nov 2020 19:15:49

US3512063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	07 Nov 2020 19:15:49

US3512063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	07 Nov 2020 19:15:49

US3512063

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	07 Nov 2020 19:15:56

US3512063

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Nov 2020 19:15:56

US3512063

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:54

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Brenda Anderson (b) (4)	14 Oct 2020 11:25:59
	(b) (4)	

US3512063

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:54

[Time of Contact](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 11:26:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 11:26:58
User entered '14:06' reason for change: Data Entry Error	Brenda Anderson (b) (4)	14 Oct 2020 11:26:58
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 11:25:59
User entered empty.	Brenda Anderson (b) (4)	14 Oct 2020 11:25:59

US3512063

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:54

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 14:06'	System	14 Oct 2020 11:26:58
User entered empty.	System	14 Oct 2020 11:25:59

US3512063

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:54

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinic Visit - Scheduled (Clinic Visit - Brenda Anderson Scheduled)'	(b) (4) (b) (4)	(b) (4) 14 Oct 2020 11:25:59

US3512063

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:54

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	14 Oct 2020 11:25:59

US3512063

Folder: Covid-19 Assessment 13 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:28:54

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	14 Oct 2020 11:27:22

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:28:54

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:21
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:49
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:26:42

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:30:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:30:12
Data point term sent to Coder	System	13 Aug 2020 20:29:24
User entered 'levothyroxine'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'hypothyroidism'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '100'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Other (OTHER)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'mcg'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 23:04:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4)	13 Aug 2020 20:28:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 20:28:28
User entered 'un UNK 2004'	Brenda Anderson (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 20:28:28

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:58:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:58:16
Data point term sent to Coder	System	13 Aug 2020 20:58:00
User entered 'omeprazole'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'heartburn'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '20'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (2015). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 08:13:15
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (2015). Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'changed per source' (Site from DM).	Brenda Anderson (b) (4)	08 Oct 2020 20:52:51
User entered 'UN UNK 2015' reason for change: Data Entry Error	Brenda Anderson (b) (4)	08 Oct 2020 20:52:39
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (2015). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 05:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 23:05:03
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is	Brenda Anderson (b) (4)	13 Aug 2020 20:57:30
' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 20:57:17
User entered 'un UNK 2005'	Brenda Anderson (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 20:57:17

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
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: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 21:01:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 21:01:12
Data point term sent to Coder	System	13 Aug 2020 21:00:07
User entered 'vitamin d'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please confirm if this indication is the same with MH#6 VITAMIN DEFICIENCY. If yes, please update indication same with the MH condition so there is an appropriate match. Update eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 08:13:29
Query 'Per DM CLR: Please confirm if this indication is the same with MH#6 VITAMIN DEFICIENCY. If yes, please update indication same with the MH condition so there is an appropriate match. Update eCRFs as appropriate.' answered with 'correct mH' (Site from DM).	Brenda Anderson (b) (4)	08 Oct 2020 20:52:07
User opened query 'Per DM CLR: Please confirm if this indication is the same with MH#6 VITAMIN DEFICIENCY. If yes, please update indication same with the MH condition so there is an appropriate match. Update eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 05:12:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'vitamin d deficiency'	Brenda Anderson (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '2000'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 23:05:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4)	13 Aug 2020 20:59:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 20:59:07
User entered 'un UNK 2019'	Brenda Anderson (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 20:59:07

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 10:18:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 10:18:18
Data point term sent to Coder	System	13 Aug 2020 21:01:11
User entered 'turmeric'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'supplement'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '2'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'tablet (TABLET)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 23:05:10
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4)	13 Aug 2020 21:00:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 21:00:48
User entered 'un Nov 2019'	Brenda Anderson (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 21:00:48

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 21:05:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 21:05:14
Data point term sent to Coder	System	13 Aug 2020 21:04:19
User entered 'ibuprofen'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'osteoarthritis'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '800'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'as needed (PRN)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 23:05:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 21:03:25
User entered 'un Sep 2019'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:03:25

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the specific type of Allegra-D (e.g., 24 Hour Allegra-D, 12 Hour Allegra-D , etc) as there are multiple dosage for this drug. Update the Medication Name field as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 08:32:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA D 24 HOUR - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Oct 2020 16:38:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Oct 2020 16:38:35
Query 'Per DM CLR: Please provide the specific type of Allegra-D (e.g., 24 Hour Allegra-D, 12 Hour Allegra-D , etc) as there are multiple dosage for this drug. Update the Medication Name field as appropriate.' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4)	14 Oct 2020 11:21:52
Data point term sent to Coder	System	14 Oct 2020 11:21:51
Coding entries removed.	Brenda Anderson (b) (4)	14 Oct 2020 11:21:45
User entered '24 hour ALLEGRA D' reason for change: New Information	Brenda Anderson (b) (4)	14 Oct 2020 11:21:45
User opened query 'Per DM CLR: Please provide the specific type of Allegra-D (e.g., 24 Hour Allegra-D, 12 Hour Allegra-D , etc) as there are multiple dosage for this drug. Update the Medication Name field as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 05:13:27
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA D - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 21:06:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 21:06:17
Data point term sent to Coder	System	13 Aug 2020 21:05:23
User entered 'allegra d'	Brenda Anderson (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'seasonal allergies'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '1'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'tablet (TABLET)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 23:05:17
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4)	13 Aug 2020 21:04:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 21:04:39
User entered 'un UNK 2019'	Brenda Anderson (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 21:04:39

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 21:08:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 21:08:17
Data point term sent to Coder	System	13 Aug 2020 21:07:25
User entered 'Flonase'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'seasonal allergies'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '2'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Other (OTHER)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'spray'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 17:25:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 17:25:23
User entered 'once daily (QD)' reason for change: Data Entry Error	Taylor Johnson (b) (4)	15 Aug 2020 17:25:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	13 Aug 2020 21:06:47
	Brenda Anderson (b) (4)	13 Aug 2020 21:06:47
	(b) (4)	

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '01 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 13:51:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 17:25:23
User entered empty.	System	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 17:25:23
User entered empty.	System	13 Aug 2020 21:06:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 17:25:23
User entered empty.	System	13 Aug 2020 21:06:47

US3512063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:28:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	01 Oct 2020 13:45:06

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:28:54

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	14 Oct 2020 11:31:04

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:28:54

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Due to SARS-COV-2 (COVID)'	Brenda Anderson (b) (4) (b) (4)	14 Oct 2020 11:31:04

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:28:54

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	14 Oct 2020 11:31:04
	(b) (4)	