

US3812280 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:56:03

All time stamps listed in this document are displayed in GMT

US3812280

Form: Participant Creation

Generated On: 26 Nov 2020 09:56:03

[Participant ID](#)

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

US3812280

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	27 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 09:56:03

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	29
Age Units	YEARS
Age (Derived)	29
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:56:03

Date of Informed Consent (<i>dd MMM yyyy</i>)	27 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 09:56:03

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:56:03

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:56:03

Condition	GERD
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 (2)

Generated On: 26 Nov 2020 09:56:03

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:56:03

Condition	ENVIRONMENTAL ALLERGIES
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 (4)

Generated On: 26 Nov 2020 09:56:03

Condition	POLYCYSTIC OVARIAN SYNDROME
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:56:03

Condition	BILATERAL LE SWELLING
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:56:03

Condition	STAGE 0 CERVICAL CA
Start date (dd MMM yyyy)	UN AUG 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2014
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2014
Start Year (derived)	2014
Stop Month and Year (derived)	AUG 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:56:03

Condition	LEEP PROCEDURE (LOOP ELECTROSURGICAL EXCISION PROCEDURE)
Start date (dd MMM yyyy)	UN AUG 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2014
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2014
Start Year (derived)	2014
Stop Month and Year (derived)	AUG 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:56:03

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN APR 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN APR 2014
Stop date completely unknown	False
Start Month and Year (derived)	APR 2014
Start Year (derived)	2014
Stop Month and Year (derived)	APR 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:56:03

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	UN APR 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN APR 2014
Stop date completely unknown	False
Start Month and Year (derived)	APR 2014
Start Year (derived)	2014
Stop Month and Year (derived)	APR 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:56:03

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

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:56:03

Condition	ANEMIA
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:56:03

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:56:03

Condition	SEIZURE
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:56:03

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:56:03

Condition	SINUS ARRHYTHMIA
Start date (dd MMM yyyy)	27 AUG 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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:56:03

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:56:03

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

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Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:56:03

Condition	ALLERGY TO SULFA
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)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:56:03

Condition	SCOLIOSIS
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:56:03

Condition	FATIGUE
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:56:03

Condition	RECURRENT SUICIDAL IDEATION
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:56:03

Condition	AUTISM SPECTRUM DISORDER
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:56:03

Condition	INTERMITTENT DIZZINESS
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 (24)

Generated On: 26 Nov 2020 09:56:03

Condition	AUDITORY HALLUCINATIONS
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:27 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 11:27
Height (<i>xxx.x</i>)	68 in
Weight (<i>xxx.x</i>)	203.6 lb
BMI (<i>xxx.x</i>)	31.02200 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	86 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 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 09:56:03

Date of assessment (*dd MMM yyyy*) 27 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 09:56:03

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	27 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 09:56:03

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 09:56:03

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	27 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 09:56:03

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 109153

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 09:56:03

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 09:56:03

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)	27 AUG 2020
Time of assessment (00:00-23:59)	11:27 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 11:27
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

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)	27 AUG 2020
Time of assessment (00:00-23:59)	13:29 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 13:29
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

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 09:56:03

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 09:56:03

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 12:58 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 12:58

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 09:56:03

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

27 AUG 2020

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

12:45 (24 HR)

Collection date and time (derived)

27 AUG 2020 12:45

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:56:03

Collection date (<i>dd MMM yyyy</i>)			27 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	12:47	27 AUG 2020 12:47
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

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 09:56:03

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 13:33

PC Open Date & Time

27 AUG 2020 13:18

PC Close Date & Time

27 AUG 2020 15:48

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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 98.7 °F

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

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

PC Time Stamp	27 AUG 2020 18:05
PC Open Date & Time	27 AUG 2020 16:43
PC Close Date & Time	28 AUG 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 16:53

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 12:59

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 15:48

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 00:48

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

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

01 SEP 2020 16:47

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 18:21

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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

27 AUG 2020 13:34

PC Open Date & Time

27 AUG 2020 13:18

PC Close Date & Time

27 AUG 2020 15:48

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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

27 AUG 2020 18:05

PC Open Date & Time

27 AUG 2020 16:43

PC Close Date & Time

28 AUG 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

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

28 AUG 2020 16:55

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

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

29 AUG 2020 12:59

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 15:49

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

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

01 SEP 2020 00:46

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

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

01 SEP 2020 16:48

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

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

02 SEP 2020 18:21

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 13:36
PC Open Date & Time	27 AUG 2020 13:18
PC Close Date & Time	27 AUG 2020 15:48

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 18:05
PC Open Date & Time	27 AUG 2020 16:43
PC Close Date & Time	28 AUG 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

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 ☒

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

Yes ☐	
PC Time stamp	28 AUG 2020 16:57
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

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 ☒

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

Yes ☐	
PC Time stamp	29 AUG 2020 13:00
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

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 ☒

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

Yes ☐	
PC Time stamp	30 AUG 2020 15:50
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

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 ☒

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

Yes ☐	
PC Time stamp	01 SEP 2020 00:46
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

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 ☒

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

Yes ☐	
PC Time stamp	01 SEP 2020 16:49
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

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 ☒

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

Yes ☐	
PC Time stamp	02 SEP 2020 18:22
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3812280

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

Was Contact Attempted?

Yes ☒

No ☐

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

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812280

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812280

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812280

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812280

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812280

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812280

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	13:37 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 13:37
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	14:53 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 14:53
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3812280

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

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.

US3812280

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	24 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3812280

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

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)	24 SEP 2020
What was the treatment time? (00:00-23:59)	14:15 (24 HR)
Treatment Date and Time (derived)	24 SEP 2020 14:15
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

US3812280

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:56:03

Collection date (<i>dd MMM yyyy</i>)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:05	24 SEP 2020 14:05
Nasopharyngeal Swab 2	No		

US3812280

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp 24 SEP 2020 14:49

PC Open Date & Time 24 SEP 2020 14:35

PC Close Date & Time 24 SEP 2020 17:05

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 22:29

PC Open Date & Time

24 SEP 2020 18:00

PC Close Date & Time

25 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	25 SEP 2020 15:19
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °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

26 SEP 2020 13:22

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 00:01

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 14:25

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 18:42

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

01 OCT 2020 08:44

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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

24 SEP 2020 14:49

PC Open Date & Time

24 SEP 2020 14:35

PC Close Date & Time

24 SEP 2020 17:05

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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

24 SEP 2020 22:27

PC Open Date & Time

24 SEP 2020 18:00

PC Close Date & Time

25 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

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

25 SEP 2020 15:19

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

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

26 SEP 2020 13:22

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 23:59

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

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

28 SEP 2020 14:25

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

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

29 SEP 2020 18:42

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

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

01 OCT 2020 08:44

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 14:51
PC Open Date & Time	24 SEP 2020 14:35
PC Close Date & Time	24 SEP 2020 17:05

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 22:27
PC Open Date & Time	24 SEP 2020 18:00
PC Close Date & Time	25 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

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 ☒

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

Yes ☐	
PC Time stamp	25 SEP 2020 15:20
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

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 ☒

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

Yes ☐	
PC Time stamp	26 SEP 2020 13:22
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

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 ☒

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

Yes ☐	
PC Time stamp	27 SEP 2020 23:59
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

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 ☒

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

Yes ☐	
PC Time stamp	28 SEP 2020 14:25
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

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 ☒

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

Yes ☐	
PC Time stamp	29 SEP 2020 18:43
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

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 ☒

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

Yes ☐	
PC Time stamp	01 OCT 2020 08:44
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3812280

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812280

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812280

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812280

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812280

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812280

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812280

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	29 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:20 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 14:20
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	93 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812280

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 OCT 2020

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

US3812280

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	29 OCT 2020
Collection time (<i>00:00-23:59</i>)	14:30 (24 HR)
Collection date and time (derived)	29 OCT 2020 14:30

US3812280

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	27 OCT 2020 13:46:26
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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	03 NOV 2020 18:45:08
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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	10 NOV 2020 22:42:40
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

Date and time of submission

23 NOV 2020 15:21:28

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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06 JAN 2021 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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13 JAN 2021 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

Please contact your study clinic immediately. Click below to confirm that you have read this 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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16 JAN 2021 00:01

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20 JAN 2021 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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27 JAN 2021 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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03 FEB 2021 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 MAR 2021 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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17 MAR 2021 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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24 MAR 2021 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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31 MAR 2021 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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07 APR 2021 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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19 JAN 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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02 FEB 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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

Date and time of submission

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05 FEB 2022 00:01

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09 FEB 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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

Date and time of submission

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12 FEB 2022 00:01

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16 FEB 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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Date and time of submission

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02 MAR 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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09 MAR 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

Date and time of submission

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12 MAR 2022 00:01

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16 MAR 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

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23 MAR 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

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30 MAR 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

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06 APR 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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Date and time of submission

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13 APR 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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16 APR 2022 00:01

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20 APR 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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°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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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°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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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27 JUL 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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03 AUG 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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17 AUG 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

Please contact your study clinic immediately. Click below to confirm that you have read this 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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24 AUG 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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

Date and time of submission

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14 SEP 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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21 SEP 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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28 SEP 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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05 OCT 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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

Date and time of submission

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12 OCT 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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19 OCT 2022 23:59

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

Please contact your study clinic immediately. Click below to confirm that you have read this 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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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3812280

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

Was Contact Attempted?

Yes ☒

No ☐

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

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812280

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812280

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:56:03

Date of Contact	19 NOV 2020
Time of Contact	13:40
Date and Time of Contact (derived)	19 NOV 2020 13:40
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 ☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	358 of 3097	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	362 of 3097	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	366 of 3097	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	370 of 3097	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	374 of 3097	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	378 of 3097	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	382 of 3097	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	386 of 3097	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	390 of 3097	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	99.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	394 of 3097	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	398 of 3097	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

Date of Visit	19 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Date of Test	14 NOV 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☒ No ☐
If yes, provide lab information below	
Lab/ Institution Test Performed	SLU HOSPITAL
CLIA Certified?	Yes ☒ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

If Yes to either Did subject require any of the following:

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date _____

End Date _____

Mechanical Ventilation? Yes ☐ No ☒

Start Date _____

End Date _____

ECMO? Yes ☐ No ☒

Start Date _____

End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date _____

Hepatic Dysfunction? Yes ☐ No ☒

Start Date _____

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:56:03

Date of Contact	22 OCT 2020
Time of Contact	13:30
Date and Time of Contact (derived)	22 OCT 2020 13:30
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 ☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	407 of 3097	

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	411 of 3097	

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	415 of 3097	

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	419 of 3097	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	423 of 3097	

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	427 of 3097	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	431 of 3097	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	435 of 3097	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	439 of 3097	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

Date of Visit	22 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☒
Date of Test	22 OCT 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:56:03

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:56:03

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	24 OCT 2020
Day 5	Yes	26 OCT 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit (2)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:56:03

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	21 NOV 2020
Day 5	Yes	23 NOV 2020
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3812280

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	22 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:13 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 14:13
Height (<i>xxx.x</i>)	67.0 in
Weight (<i>xxx.x</i>)	204.0 lb
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812280

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3812280

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:56:03

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

22 OCT 2020

US3812280

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	19 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	19 NOV 2020
Time of assessment (00:00-23:59)	14:23 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 14:23
Height (xxx.x)	67.0 in
Weight (xxx.x)	195.8 lb
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	112 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812280

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 NOV 2020

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

US3812280

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:56:03

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 NOV 2020

US3812280

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3812280

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

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.

US3812280

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:56:03

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3812280

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:56:03

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

AEID	
Adverse event	GERD EXACERBATION
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	26 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	10 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

19 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

AEID	
Adverse event	WORSENING DEPRESSION
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	05 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	27 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

AEID	USA-US111-2020-MRNA-1273-P30 1000009
Adverse event	WORSENING DEPRESSION
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	12 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	17 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	17 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

THIS IS A 30-YEAR-OLD
FEMALE WHO WAS
HOSPITALIZED ON 13
NOVEMBER 2020 WITH AN
ADMITTING DIAGNOSIS OF
“MAJOR DEPRESSIVE DISORDER
WITH SUICIDAL IDEATION.”
PER MEDICAL RECORDS, THE
SUBJECT HAD PLANNED TO

(b) (6)

THE SUBJECT HAS A
HISTORY OF ANXIETY,
DEPRESSION, RECURRENT
SUICIDAL IDEATION,
NON-COMMAND AUDITORY
HALLUCINATIONS, AND
CHRONIC FATIGUE. PERTINENT
LABS INCLUDE A NEGATIVE
URINE DRUG SCREEN AND A
POSITIVE COVID-19 RAPID
TEST. TWO SUBSEQUENT
COVID-19 ANTIBODY TESTS
WERE NEGATIVE. MEDICAL
RECORDS DID NOT NOTATE
WHAT MEDICATIONS WERE
TAKEN BY THE SUBJECT
DURING THIS
HOSPITALIZATION. SUBJECT
WAS DISCHARGED IN STABLE
CONDITION ON 17 NOVEMBER
2020 AND WAS ADVISED TO
FOLLOW UP WITH PSYCHIATRY
IN ONE MONTH. THE SUBJECT
WAS DISCHARGED WITH THE
FOLLOWING MEDICATIONS:
ARIPIRAZOLE 2 MG ONCE
DAILY, BUPROPION XL 300 MG
Q HS, ACETAMINOPHEN 650 MG
Q 4 HRS PRN, AND CALCIUM
CARBONATE 1 G Q 4 HRS PRN.

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

v6.020 DTW (1102)

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US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

AEID	USA-US111-2020-MRNA-1273-P30 1000009
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☒ No ☐
Start date (dd MMM yyyy)	13 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

		SUBJECT 2280 HAD A POSITIVE COVID-19 RAPID TEST FROM A CLIA CERTIFIED LAB ON 14 NOVEMBER 2020. SUBJECT WAS BROUGHT IN FOR AN ILLNESS VISIT ON 19NOV2020 FOR NEW COVID-19 RELATED SX AND RECENT EXPOSURE TO SOMEONE WHO WAS COVID-19 POSTIVE. CENTRAL LAB RESULTS FROM THAT ILLNESS VISIT SHOWED A NEGATIVE COVID PCR SWAB.
Serious Adverse Event Derived (CSA Programming Field Only)		0
Medically Attended AE Derived (CSA Programming Field Only)		1
Admitted to ICU Derived (CSA Programming Field Only)		

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:56:03

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

Yes ☒

No ☐

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

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	GERD
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	WELLBUTRIN XL
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
Dose per administration	150
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

	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 AUG 2016	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
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	☒

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

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

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	19 OCT 2020	
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	☒

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	SPIRENOLACTONE
Prophylaxis	Yes ☐ No ☒
Indication	BILATERAL LE SWELLING
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

	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 DEC 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	☒

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ☒ No ☐
Indication	GENERAL HEALTH
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

	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 DEC 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	☒

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	IUD
Prophylaxis	Yes ☒
	No ☐
Indication	CONTRACEPTION
Dose per administration	1
Dose unit	mg ☐
	ug ☐
	mL ☐
	g ☐
	IU ☐
	tablet ☐
	capsule ☐
	puff ☐
	Other ☒
If dose unit is Other, specify	UNIT
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	ONCE EVERY FIVE YEARS
Route of administration	Oral ☐
	Topical ☐
	Subcutaneous ☐
	Transdermal ☐
	Intraocular ☐
	Intramuscular ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	INTRAUTERINE	
Start date (dd MMM yyyy)	14 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	WELLBUTRIN XL
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
Dose per administration	300
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

	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)		20 OCT 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	☒

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	VITAMIN C
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
Dose per administration	400
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

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)	20 OCT 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 ☒

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	VITAMIN D3
Prophylaxis	Yes ☒ No ☐
Indication	GENERAL HEALTH
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

	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)		20 OCT 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	☒

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	ZYRTEC
Prophylaxis	Yes ☐ No ☒
Indication	ENVIRONMENTAL ALLERGIES
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

	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)		20 OCT 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	☒

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	FEVER
Dose per administration	400
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

	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)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		25 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	NAPROXEN
Prophylaxis	Yes ☐ No ☒
Indication	FEVER
Dose per administration	250
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

	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)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		25 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	400
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

	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)		16 OCT 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	SORE THROAT
Dose per administration	400
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

	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)		16 OCT 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	EXCEDRIN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

	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)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	EXCEDRIN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

	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)		25 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		25 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	CEPACOL LOZENGE
Prophylaxis	Yes ☐ No ☒
Indication	SORE THROAT
Dose per administration	4
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	DOSES
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

	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)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	ABILIFY
Prophylaxis	Yes ☐ No ☒
Indication	MAJOR DEPRESSIVE DISORDER
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

	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)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	400
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

	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)	21 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 21 NOV 2020		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	CALCIUM CARBONATE
Prophylaxis	Yes ☐ No ☒
Indication	GERD
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

	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)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHES
Dose per administration	650
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 ☐

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

	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)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812280

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:56:03

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3812280

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:56:03

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3812280

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:56:03

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 ☐

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

SAEID	USA-US111-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:56:03

SAEID	USA-US111-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	17/NOV/2020 09:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:56:03

SAEID	USA-US111-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/NOV/2020 10:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:56:03

SAEID	USA-US111-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	23/NOV/2020 16:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3812280 (Prod: Sundance Clinical Research - Platinum - PPDS)

US3812280

Form: Participant Creation

Generated On: 26 Nov 2020 09:56:03

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3812280'	RWS_ENDPOINT ENDPOINT (b) (4) 	27 Aug 2020 16:19:49

US3812280

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	27 Aug 2020 18:07:35

US3812280

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	27 Aug 2020 16:19:50

US3812280

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	27 Aug 2020 18:07:35

US3812280

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	27 Aug 2020 18:07:35

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1990'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	27 Aug 2020 16:19:51

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[Age](#)

Audit	User	Time (GMT)
User entered '29'	Heather Cherniawski (b) (4)	27 Aug 2020 18:12:53

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	27 Aug 2020 18:12:53

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '29'	System	27 Aug 2020 18:07:48

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Heather Cherniawski (b) (4)	27 Aug 2020 18:12:53

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Heather Cherniawski (b) (4)	27 Aug 2020 18:12:53

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[White](#)

Audit	User	Time (GMT)
User entered '1'	Heather Cherniawski (b) (4)	27 Aug 2020 18:12:53

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	27 Aug 2020 18:12:53

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	27 Aug 2020 18:12:53

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	27 Aug 2020 18:12:53

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	27 Aug 2020 18:12:53

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	27 Aug 2020 18:12:53

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	27 Aug 2020 18:12:53

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	27 Aug 2020 18:12:53

US3812280

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:56:03

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	27 Aug 2020 18:12:53

US3812280

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Heather Cherniawski (b) (4)	27 Aug 2020 18:07:48

US3812280

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	27 Aug 2020 18:07:48

US3812280

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2020'	System	27 Aug 2020 18:07:48

US3812280

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:56:03

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Heather Cherniawski (b) (4)	27 Aug 2020 18:07:48

US3812280

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	27 Aug 2020 18:07:48

US3812280

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	27 Aug 2020 18:07:48

US3812280

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:56:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	27 Aug 2020 18:07:48

US3812280

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:56:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	27 Aug 2020 18:07:48

US3812280

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:56:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	27 Aug 2020 16:19:50

US3812280

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:56:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 18:07:54

US3812280

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	27 Aug 2020 18:07:54

US3812280

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:56:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:02

US3812280

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:56:03

[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: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:08:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:08:48
Data point term sent to Coder	System	29 Aug 2020 19:08:12
User entered 'GERD'	Karen Knapp (b) (4)	29 Aug 2020 19:07:17
	(b) (4)	

US3812280

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:17

US3812280

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:17

US3812280

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:17

US3812280

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:17

US3812280

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:17

US3812280

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	29 Aug 2020 19:07:17

US3812280

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2010'	System	29 Aug 2020 19:07:17

US3812280

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:07:17

US3812280

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:07:17

US3812280

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:08:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:08:48
Data point term sent to Coder	System	29 Aug 2020 19:08:11
User entered 'DEPRESSION'	Karen Knapp (b) (4)	29 Aug 2020 19:07:27
	(b) (4)	

US3812280

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:27

US3812280

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:27

US3812280

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:27

US3812280

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:27

US3812280

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:27

US3812280

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	29 Aug 2020 19:07:27

US3812280

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '1998'	System	29 Aug 2020 19:07:27

US3812280

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:07:27

US3812280

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:07:27

US3812280

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4)	29 Aug 2020 19:08:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Aug 2020 19:08:48
Data point term sent to Coder	System	29 Aug 2020 19:08:11
User entered 'ENVIRONMENTAL ALLERGIES'	Karen Knapp (b) (4)	29 Aug 2020 19:07:45

US3812280

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:45

US3812280

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:45

US3812280

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:45

US3812280

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:45

US3812280

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:07:45

US3812280

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	29 Aug 2020 19:07:45

US3812280

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2000'	System	29 Aug 2020 19:07:45

US3812280

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:07:45

US3812280

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:07:45

US3812280

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLG: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Polycystic ovaries, LLT: Polycystic ovarian syndrome - version MedDRA\23.0.	Coder Import (b) (4)	29 Aug 2020 19:09:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Aug 2020 19:09:49
Data point term sent to Coder	System	29 Aug 2020 19:09:12
User entered 'POLYCYSTIC OVARIAN SYNDROME'	Karen Knapp (b) (4)	29 Aug 2020 19:08:13

US3812280

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Dec 2019'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:13

US3812280

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:13

US3812280

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:13

US3812280

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:13

US3812280

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:13

US3812280

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Dec 2019'	System	29 Aug 2020 19:08:13

US3812280

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2019'	System	29 Aug 2020 19:08:13

US3812280

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:08:13

US3812280

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:08:13

US3812280

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Swelling of legs - version MedDRA\\23.0.	Coder Import (b) (4)	30 Aug 2020 05:33:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Aug 2020 05:33:49
Data point term sent to Coder	System	29 Aug 2020 19:09:12
User entered 'BILATERAL LE SWELLING'	Karen Knapp (b) (4)	29 Aug 2020 19:08:26

US3812280

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Dec 2019'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:26

US3812280

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:26

US3812280

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:26

US3812280

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:26

US3812280

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:26

US3812280

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Dec 2019'	System	29 Aug 2020 19:08:26

US3812280

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2019'	System	29 Aug 2020 19:08:26

US3812280

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:08:26

US3812280

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:08:26

US3812280

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female malignant and unspecified, HLT: Cervix neoplasms malignant, PT: Cervix carcinoma stage 0, LLT: Cervical cancer stage 0 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:31:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:31:50
Data point term sent to Coder	System	29 Aug 2020 19:09:13
User entered 'STAGE 0 CERVICAL CA'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:52

US3812280

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Aug 2014'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:52

US3812280

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:52

US3812280

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:52

US3812280

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Aug 2014'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:52

US3812280

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:08:52

US3812280

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Aug 2014'	System	29 Aug 2020 19:08:52

US3812280

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2014'	System	29 Aug 2020 19:08:52

US3812280

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Aug 2014'	System	29 Aug 2020 19:08:52

US3812280

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2014'	System	29 Aug 2020 19:08:52

US3812280

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:56:03

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Cervix therapeutic procedures, PT: Loop electrosurgical excision procedure, LLT: Loop electrosurgical excision procedure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 06:59:11
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 06:59:11
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 15:45:28
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'stage 0 cervical cancer recorded' (Site from DM).	Anya Penly (b) (4) (b) (4)	30 Oct 2020 19:58:14
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 17:28:05
User closed query 'Per MM, please expand the abbreviation. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:33:58
Data point term sent to Coder	System	07 Oct 2020 13:46:07
Query 'Per MM, please expand the abbreviation. ' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	07 Oct 2020 13:46:00
Coding entries removed.	Angie Kean (b) (4) (b) (4)	07 Oct 2020 13:45:55
User entered 'LEEP PROCEDURE (LOOP ELECTROSURGICAL EXCISION PROCEDURE)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	07 Oct 2020 13:45:55
User opened query 'Per MM, please expand the abbreviation. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:01:10

US3812280

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Cervix therapeutic procedures, PT: Loop electrosurgical excision procedure, LLT: Loop electrosurgical excision procedure - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:10:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:10:38
Data point term sent to Coder	System	29 Aug 2020 19:10:13
User entered 'LEEP PROCEDURE' reason for change: Data Entry Error	Karen Knapp (b) (4)	29 Aug 2020 19:09:43
User entered 'LEEP PEROCEDURE'	Karen Knapp (b) (4)	29 Aug 2020 19:09:16

US3812280

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Aug 2014'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:09:16

US3812280

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:09:16

US3812280

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	29 Aug 2020 19:09:27
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:09:27
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	29 Aug 2020 19:09:16
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:09:16

US3812280

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Aug 2014'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:09:16

US3812280

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:09:16

US3812280

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Aug 2014'	System	29 Aug 2020 19:09:16

US3812280

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2014'	System	29 Aug 2020 19:09:16

US3812280

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Aug 2014'	System	29 Aug 2020 19:09:16

US3812280

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2014'	System	29 Aug 2020 19:09:16

US3812280

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\23.0.	Coder Import (b) (4)	29 Aug 2020 19:10:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Aug 2020 19:10:38
Data point term sent to Coder	System	29 Aug 2020 19:10:13
User entered 'CHOLECYSTECTOMY'	Karen Knapp (b) (4)	29 Aug 2020 19:10:05

US3812280

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Apr 2014'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:05

US3812280

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:05

US3812280

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:05

US3812280

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Apr 2014'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:05

US3812280

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:05

US3812280

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Apr 2014'	System	29 Aug 2020 19:10:05

US3812280

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2014'	System	29 Aug 2020 19:10:05

US3812280

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Apr 2014'	System	29 Aug 2020 19:10:05

US3812280

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2014'	System	29 Aug 2020 19:10:05

US3812280

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:12:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:12:39
Data point term sent to Coder	System	29 Aug 2020 19:11:14
User entered 'CHOLECYSTITIS'	Karen Knapp (b) (4)	29 Aug 2020 19:10:25

US3812280

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Apr 2014'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:25

US3812280

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:25

US3812280

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:25

US3812280

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Apr 2014'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:25

US3812280

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:25

US3812280

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Apr 2014'	System	29 Aug 2020 19:10:25

US3812280

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2014'	System	29 Aug 2020 19:10:25

US3812280

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Apr 2014'	System	29 Aug 2020 19:10:25

US3812280

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2014'	System	29 Aug 2020 19:10:25

US3812280

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual impairment, LLT: Visual impairment - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:12:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:12:39
Data point term sent to Coder	System	29 Aug 2020 19:11:17
User entered 'BILATERAL VISION IMPAIRMENT'	Karen Knapp (b) (4)	29 Aug 2020 19:10:45

US3812280

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:45

US3812280

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:45

US3812280

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:45

US3812280

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:45

US3812280

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:45

US3812280

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 19:10:45

US3812280

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 19:10:45

US3812280

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:10:45

US3812280

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:10:45

US3812280

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:56:03

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:12:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:12:39
Data point term sent to Coder	System	29 Aug 2020 19:11:16
User entered 'ANEMIA'	Karen Knapp (b) (4)	29 Aug 2020 19:10:56
	(b) (4)	

US3812280

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 2002'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:56

US3812280

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:56

US3812280

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:56

US3812280

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:56

US3812280

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:10:56

US3812280

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	29 Aug 2020 19:10:56

US3812280

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2002'	System	29 Aug 2020 19:10:56

US3812280

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:10:56

US3812280

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:10:56

US3812280

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:12:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:12:39
Data point term sent to Coder	System	29 Aug 2020 19:11:16
User entered 'MIGRAINES'	Karen Knapp (b) (4)	29 Aug 2020 19:11:09
	(b) (4)	

US3812280

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 2006'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:09

US3812280

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:09

US3812280

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:09

US3812280

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:09

US3812280

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:09

US3812280

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	29 Aug 2020 19:11:09

US3812280

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2006'	System	29 Aug 2020 19:11:09

US3812280

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:11:09

US3812280

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:11:09

US3812280

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizure - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:13:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:13:39
Data point term sent to Coder	System	29 Aug 2020 19:12:17
User entered 'SEIZURE'	Karen Knapp (b) (4)	29 Aug 2020 19:11:26
	(b) (4)	

US3812280

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 2002'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:26

US3812280

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:26

US3812280

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:26

US3812280

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 2002'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:26

US3812280

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:26

US3812280

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	29 Aug 2020 19:11:26

US3812280

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2002'	System	29 Aug 2020 19:11:26

US3812280

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	29 Aug 2020 19:11:26

US3812280

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2002'	System	29 Aug 2020 19:11:26

US3812280

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:13:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:13:39
Data point term sent to Coder	System	29 Aug 2020 19:12:17
User entered 'HYPERLIPIDEMIA'	Karen Knapp (b) (4)	29 Aug 2020 19:11:41

US3812280

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Dec 2019'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:41

US3812280

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:41

US3812280

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:41

US3812280

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:41

US3812280

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:11:41

US3812280

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Dec 2019'	System	29 Aug 2020 19:11:41

US3812280

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2019'	System	29 Aug 2020 19:11:41

US3812280

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:11:41

US3812280

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:11:41

US3812280

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus arrhythmia, LLT: Sinus arrhythmia - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:13:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 19:13:39
Data point term sent to Coder	System	29 Aug 2020 19:13:18
User entered 'SINUS ARRHYTHMIA'	Karen Knapp (b) (4)	29 Aug 2020 19:12:29

US3812280

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:12:29

US3812280

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:12:29

US3812280

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:12:29

US3812280

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:12:29

US3812280

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:12:29

US3812280

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	29 Aug 2020 19:12:29

US3812280

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2020'	System	29 Aug 2020 19:12:29

US3812280

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:12:29

US3812280

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:12:29

US3812280

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:56:03

[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)	30 Sep 2020 17:24:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 17:24:01
Data point term sent to Coder	System	30 Sep 2020 17:22:56
User entered 'back pain'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:22:40

US3812280

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'un UNK 2001'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:22:40

US3812280

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:22:40

US3812280

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:22:40

US3812280

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:22:40

US3812280

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:22:40

US3812280

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	30 Sep 2020 17:22:40

US3812280

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2001'	System	30 Sep 2020 17:22:40

US3812280

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:22:40

US3812280

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:22:40

US3812280

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 17:25:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 17:25:04
Data point term sent to Coder	System	30 Sep 2020 17:24:01
User entered 'anxiety'	Breanna Galibert (b) (4)	30 Sep 2020 17:23:01
	(b) (4)	

US3812280

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'un UNK 1998'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:01

US3812280

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:01

US3812280

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:01

US3812280

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:01

US3812280

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:01

US3812280

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	30 Sep 2020 17:23:01

US3812280

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '1998'	System	30 Sep 2020 17:23:01

US3812280

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:23:01

US3812280

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:23:01

US3812280

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:56:03

[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: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 17:25:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 17:25:05
Data point term sent to Coder	System	30 Sep 2020 17:24:01
User entered 'allergy to sulfa'	Breanna Galibert (b) (4)	30 Sep 2020 17:23:14

US3812280

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'un UNK 1995'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:14

US3812280

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:14

US3812280

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:14

US3812280

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:14

US3812280

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:14

US3812280

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	30 Sep 2020 17:23:14

US3812280

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '1995'	System	30 Sep 2020 17:23:14

US3812280

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:23:14

US3812280

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:23:14

US3812280

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Scoliosis, LLT: Scoliosis - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 17:25:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 17:25:05
Data point term sent to Coder	System	30 Sep 2020 17:24:02
User entered 'scoliosis'	Breanna Galibert (b) (4)	30 Sep 2020 17:23:36
	(b) (4)	

US3812280

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'un UNK 2001'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:36

US3812280

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:36

US3812280

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:36

US3812280

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:36

US3812280

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:36

US3812280

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	30 Sep 2020 17:23:36

US3812280

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2001'	System	30 Sep 2020 17:23:36

US3812280

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:23:36

US3812280

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:23:36

US3812280

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 17:25:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 17:25:05
Data point term sent to Coder	System	30 Sep 2020 17:24:02
User entered 'fatigue'	Breanna Galibert (b) (4)	30 Sep 2020 17:23:51

US3812280

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'un UNK 2001'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:51

US3812280

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:51

US3812280

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:51

US3812280

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:51

US3812280

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:23:51

US3812280

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	30 Sep 2020 17:23:51

US3812280

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2001'	System	30 Sep 2020 17:23:51

US3812280

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:23:51

US3812280

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:23:51

US3812280

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicidal ideation, LLT: Suicidal ideation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 05:59:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 05:59:24
Data point term sent to Coder	System	23 Oct 2020 15:40:15
User entered 'RECURRENT SUICIDAL IDEATION'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:39:32

US3812280

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:39:32

US3812280

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:39:32

US3812280

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:39:32

US3812280

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:39:32

US3812280

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:39:32

US3812280

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	23 Oct 2020 15:39:32

US3812280

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '1998'	System	23 Oct 2020 15:39:32

US3812280

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	23 Oct 2020 15:39:32

US3812280

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2018'	System	23 Oct 2020 15:39:32

US3812280

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Developmental disorders NEC, HLT: Pervasive developmental disorders NEC, PT: Autism spectrum disorder, LLT: Autism spectrum disorder - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:41:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:41:31
Data point term sent to Coder	System	23 Oct 2020 15:40:18
User entered 'AUTISM SPECTRUM DISORDER'	Breanna Galibert (b) (4)	23 Oct 2020 15:40:09

US3812280

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:40:09

US3812280

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:40:09

US3812280

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:40:09

US3812280

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:40:09

US3812280

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:40:09

US3812280

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	23 Oct 2020 15:40:09

US3812280

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2018'	System	23 Oct 2020 15:40:09

US3812280

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:40:09

US3812280

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:40:09

US3812280

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:37:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:37:50
Data point term sent to Coder	System	19 Nov 2020 23:36:34
User entered 'INTERMITTENT DIZZINESS'	Breanna Galibert (b) (4)	19 Nov 2020 23:35:33

US3812280

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:35:33

US3812280

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:35:33

US3812280

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:35:33

US3812280

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:35:33

US3812280

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:35:33

US3812280

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	19 Nov 2020 23:35:33

US3812280

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2000'	System	19 Nov 2020 23:35:33

US3812280

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:35:33

US3812280

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:35:33

US3812280

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:56:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Disturbances in thinking and perception, HLT: Hallucinations (excl sleep-related), PT: Hallucination, auditory, LLT: Auditory hallucinations - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:37:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:37:51
Data point term sent to Coder	System	19 Nov 2020 23:36:33
User entered 'AUDITORY HALLUCINATIONS'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:35:52

US3812280

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:35:52

US3812280

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:35:52

US3812280

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:56:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:35:52

US3812280

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:35:52

US3812280

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:56:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:35:52

US3812280

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	19 Nov 2020 23:35:52

US3812280

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '2016'	System	19 Nov 2020 23:35:52

US3812280

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:35:52

US3812280

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:35:52

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '11:27'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:27'	System	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '68' in	Karen Knapp (b) (4)	29 Aug 2020 19:14:00
DataPoint set to visible.	(b) (4) System	27 Aug 2020 18:07:54

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '203.6' lb	Karen Knapp (b) (4)	29 Aug 2020 19:14:00
DataPoint set to visible.	(b) (4) System	27 Aug 2020 18:07:54

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '31.02200'	System	29 Aug 2020 19:14:00
DataPoint set to visible.	System	27 Aug 2020 18:07:54

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	29 Aug 2020 19:14:00
DataPoint set to visible.	System	27 Aug 2020 18:07:54

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '86'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '16'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '114'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 19:14:00

US3812280

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:12:40

US3812280

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:12:40

US3812280

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:56:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:13:04

US3812280

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:13:04

US3812280

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:13:04

US3812280

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:56:03

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:13:04

US3812280

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:13:04

US3812280

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:56:03

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:13:04

US3812280

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:13:04

US3812280

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:56:03

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:13:04

US3812280

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:20

US3812280

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:20

US3812280

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:20

US3812280

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:20

US3812280

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:20

US3812280

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:20

US3812280

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:14:20

US3812280

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:14:20

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

[Other](#)

Audit	User	Time (GMT)
User entered '1'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:56:03

[Specify](#)

Audit	User	Time (GMT)
User entered 'RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:30

US3812280

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	27 Aug 2020 18:08:08

US3812280

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Heather Cherniawski (b) (4)	27 Aug 2020 18:08:08

US3812280

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	27 Aug 2020 18:08:08

US3812280

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	27 Aug 2020 18:08:08

US3812280

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	27 Aug 2020 17:44:47

US3812280

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:56:03

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
User entered '109153'	RWS_ENDPOINT ENDPOINT (b) (4) 	27 Aug 2020 17:44:47

US3812280

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:56:03

[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) 	27 Aug 2020 17:44:47

US3812280

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:56:03

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)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:52

US3812280

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:52

US3812280

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:52

US3812280

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:56:03

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:52

US3812280

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:56:03

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:15:52

US3812280

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4)	21 Sep 2020 19:17:59
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 09:47:55
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:15:19

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:56:03

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:34:46
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.'	Angie Kean (b) (4)	24 Oct 2020 19:37:19
answered with 'UPDATED' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4)	24 Oct 2020 19:37:15
	(b) (4)	
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:59:46
User entered '67' in	Karen Knapp (b) (4)	29 Aug 2020 19:17:56
	(b) (4)	

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:56:03

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4)	24 Oct 2020 19:37:15
User entered '203.6' lb	Karen Knapp (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:56:03

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:34:46
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	24 Oct 2020 19:37:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	24 Oct 2020 19:37:15
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:59:46
User entered '67' in	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:56:03

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4)	24 Oct 2020 19:37:15
User entered '203.6' lb	Karen Knapp (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '11:27'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:27'	System	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

Pulse (xxx)

Audit	User	Time (GMT)
User entered '86'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '16'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '114'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:56:03

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:34:46
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.'	Angie Kean (b) (4)	24 Oct 2020 19:37:19
answered with 'UPDATED' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4)	24 Oct 2020 19:37:15
	(b) (4)	
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:59:46
User entered '67' in	Karen Knapp (b) (4)	29 Aug 2020 19:17:56
	(b) (4)	

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:56:03

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4)	24 Oct 2020 19:37:15
User entered '203.6' lb	Karen Knapp (b) (4)	29 Aug 2020 19:17:56

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '13:29'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 13:29'	System	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

Pulse (xxx)

Audit	User	Time (GMT)
User entered '84'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '16'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 19:18:36

US3812280

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4)	17 Sep 2020 00:19:53
User entered 'Yes (Y)'	Karen Knapp (b) (4)	29 Aug 2020 19:16:00

US3812280

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4)	17 Sep 2020 00:19:53
User entered '27 Aug 2020'	Karen Knapp (b) (4)	29 Aug 2020 19:16:00

US3812280

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at V1D1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:06:52
Query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at V1D1 to avoid duplication. Please review and update accordingly.' answered with 'UPDATED PER QUERY ' (Site from DM).	Breanna Galibert (b) (4)	06 Oct 2020 21:03:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	06 Oct 2020 21:03:26
User opened query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at V1D1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:16:59
User entered 'Yes (Y)'	Karen Knapp (b) (4)	29 Aug 2020 19:16:13

US3812280

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 21:03:26
User entered '27 Aug 2020'	Karen Knapp (b) (4)	29 Aug 2020 19:16:13

US3812280

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Test performed](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 21:03:26
User entered 'Urine (URINE)'	Karen Knapp (b) (4)	29 Aug 2020 19:16:13

US3812280

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Result](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 21:03:26
User entered 'Negative (NEGATIVE)'	Karen Knapp (b) (4)	29 Aug 2020 19:16:13

US3812280

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 21:03:26
User entered 'No (N)'	Karen Knapp (b) (4)	29 Aug 2020 19:16:13

US3812280

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:16:13

US3812280

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:16:13

US3812280

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:16:13

US3812280

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	27 Aug 2020 18:09:13

US3812280

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	27 Aug 2020 18:09:13

US3812280

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	27 Aug 2020 18:09:13

US3812280

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 18:09:13

US3812280

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Heather Cherniawski (b) (4)	27 Aug 2020 18:09:13

US3812280

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:58'	Heather Cherniawski (b) (4)	27 Aug 2020 18:09:13

US3812280

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:58'	System	27 Aug 2020 18:09:13

US3812280

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski (b) (4)	27 Aug 2020 18:09:13

US3812280

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	27 Aug 2020 18:09:13

US3812280

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 18:09:13

US3812280

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:16:27

US3812280

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:16:27

US3812280

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:45'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:16:27

US3812280

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:45'	System	29 Aug 2020 19:16:27

US3812280

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:56:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:16:41

US3812280

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:56:03

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:16:41

US3812280

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:56:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:16:41

US3812280

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:56:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:47'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:16:41

US3812280

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:47'	System	29 Aug 2020 19:16:41

US3812280

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:56:03

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:16:41

US3812280

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:56:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:16:41

US3812280

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:56:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:16:41

US3812280

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:16:41

US3812280

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:16:46

US3812280

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:16:46

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:33:01', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '80015a7d-b78f-485b-81d9-fe091b93d1b4'	System	27 Aug 2020 18:33:23
User entered 'Yes (Y)'	System	27 Aug 2020 18:33:23

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:33:06', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '80015a7d-b78f-485b-81d9-fe091b93d1b4'	System	27 Aug 2020 18:33:23
User entered '98.3'	System	27 Aug 2020 18:33:23

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:33:15', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '80015a7d-b78f-485b-81d9-fe091b93d1b4'	System	27 Aug 2020 18:33:23
User entered 'No (N)'	System	27 Aug 2020 18:33:23

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:33:21', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '80015a7d-b78f-485b-81d9-fe091b93d1b4'	System	27 Aug 2020 18:33:23
User entered '27 Aug 2020 13:33'	System	27 Aug 2020 18:33:23

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 13:18'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 15:48'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:03:50', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '74dbf1dd-e8c3-442b-b9c5-a29db1a4dcd1' User entered 'Yes (Y)'	System	27 Aug 2020 23:05:12
	System	27 Aug 2020 23:05:12

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:04:54', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '74dbf1dd-e8c3-442b-b9c5-a29db1a4dcd1' User entered '98.7'	System	27 Aug 2020 23:05:12

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:08', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '74dbf1dd-e8c3-442b-b9c5-a29db1a4dcd1'	System	27 Aug 2020 23:05:12
User entered 'No (N)'	System	27 Aug 2020 23:05:12

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:10', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '74dbf1dd-e8c3-442b-b9c5-a29db1a4dcd1'	System	27 Aug 2020 23:05:12
User entered '27 Aug 2020 18:05'	System	27 Aug 2020 23:05:12

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 16:43'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 2'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:53:16', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a3c3b1ef-4226-4635-93e4-c044861a7199'	System	28 Aug 2020 21:53:30
User entered 'Yes (Y)'	System	28 Aug 2020 21:53:30

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:53:22', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a3c3b1ef-4226-4635-93e4-c044861a7199'	System	28 Aug 2020 21:53:30
User entered '97.9'	System	28 Aug 2020 21:53:30

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:53:25', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a3c3b1ef-4226-4635-93e4-c044861a7199'	System	28 Aug 2020 21:53:30
User entered 'No (N)'	System	28 Aug 2020 21:53:30

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:53:28', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a3c3b1ef-4226-4635-93e4-c044861a7199'	System	28 Aug 2020 21:53:30
User entered '28 Aug 2020 16:53'	System	28 Aug 2020 21:53:30

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 3'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:13', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ebc9db9b-489d-417a-a2a9-7d1d3ec3b66d'	System	29 Aug 2020 17:59:21
User entered 'Yes (Y)'	System	29 Aug 2020 17:59:21

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:16', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ebc9db9b-489d-417a-a2a9-7d1d3ec3b66d' User entered '97.7'	System	29 Aug 2020 17:59:21
	System	29 Aug 2020 17:59:21

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:17', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ebc9db9b-489d-417a-a2a9-7d1d3ec3b66d'	System	29 Aug 2020 17:59:21
User entered 'No (N)'	System	29 Aug 2020 17:59:21

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:19', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ebc9db9b-489d-417a-a2a9-7d1d3ec3b66d'	System	29 Aug 2020 17:59:21
User entered '29 Aug 2020 12:59'	System	29 Aug 2020 17:59:21

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 4'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:48:09', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b31d1c22-7613-4fd8-9ee1-b023dd0db704'	System	30 Aug 2020 20:48:37
User entered 'Yes (Y)'	System	30 Aug 2020 20:48:37

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:48:12', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b31d1c22-7613-4fd8-9ee1-b023dd0db704'	System	30 Aug 2020 20:48:37
User entered '97.9'	System	30 Aug 2020 20:48:37

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:48:15', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b31d1c22-7613-4fd8-9ee1-b023dd0db704'	System	30 Aug 2020 20:48:37
User entered 'No (N)'	System	30 Aug 2020 20:48:37

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:48:35', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b31d1c22-7613-4fd8-9ee1-b023dd0db704'	System	30 Aug 2020 20:48:37
User entered '30 Aug 2020 15:48'	System	30 Aug 2020 20:48:37

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 5'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:19', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '1cea4f61-80dc-4a37-85b1-9c63c88b2454'	System	01 Sep 2020 05:48:18
User entered 'Yes (Y)'	System	01 Sep 2020 05:48:18

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:48:11', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '1cea4f61-80dc-4a37-85b1-9c63c88b2454'	System	01 Sep 2020 05:48:18
User entered '97.4'	System	01 Sep 2020 05:48:18

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:48:15', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '1cea4f61-80dc-4a37-85b1-9c63c88b2454'	System	01 Sep 2020 05:48:18
User entered 'No (N)'	System	01 Sep 2020 05:48:18

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:48:17', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '1cea4f61-80dc-4a37-85b1-9c63c88b2454'	System	01 Sep 2020 05:48:18
User entered '01 Sep 2020 00:48'	System	01 Sep 2020 05:48:18

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 6'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:47:41', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'd591d2d4-6dec-4003-9689-b61f2a74d095'	System	01 Sep 2020 21:47:51
User entered 'Yes (Y)'	System	01 Sep 2020 21:47:51

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:47:45', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'd591d2d4-6dec-4003-9689-b61f2a74d095'	System	01 Sep 2020 21:47:51
User entered '97.6'	System	01 Sep 2020 21:47:51

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:47:47', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'd591d2d4-6dec-4003-9689-b61f2a74d095'	System	01 Sep 2020 21:47:51
User entered 'No (N)'	System	01 Sep 2020 21:47:51

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:47:48', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'd591d2d4-6dec-4003-9689-b61f2a74d095'	System	01 Sep 2020 21:47:51
User entered '01 Sep 2020 16:47'	System	01 Sep 2020 21:47:51

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 7'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:03', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '6f6696b6-6124-48c9-b6b8-844d5b66fd1d'	System	02 Sep 2020 23:21:17
User entered 'Yes (Y)'	System	02 Sep 2020 23:21:17

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:06', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '6f6696b6-6124-48c9-b6b8-844d5b66fd1d'	System	02 Sep 2020 23:21:17
User entered '99.1'	System	02 Sep 2020 23:21:17

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:09', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '6f6696b6-6124-48c9-b6b8-844d5b66fd1d'	System	02 Sep 2020 23:21:17
User entered 'No (N)'	System	02 Sep 2020 23:21:17

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:14', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '6f6696b6-6124-48c9-b6b8-844d5b66fd1d'	System	02 Sep 2020 23:21:17
User entered '02 Sep 2020 18:21'	System	02 Sep 2020 23:21:17

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:34:23', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '858a96b4-cf74-4526-90cd-34c2d16b3466'	System	27 Aug 2020 18:35:03
User entered 'None (1)'	System	27 Aug 2020 18:35:03

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:34:31', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '858a96b4-cf74-4526-90cd-34c2d16b3466'	System	27 Aug 2020 18:35:03
User entered 'No (N)'	System	27 Aug 2020 18:35:03

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:34:46', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '858a96b4-cf74-4526-90cd-34c2d16b3466'	System	27 Aug 2020 18:35:03
User entered 'No (N)'	System	27 Aug 2020 18:35:03

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:34:54', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '858a96b4-cf74-4526-90cd-34c2d16b3466'	System	27 Aug 2020 18:35:03
User entered 'None (1)'	System	27 Aug 2020 18:35:03

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:34:58', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '858a96b4-cf74-4526-90cd-34c2d16b3466'	System	27 Aug 2020 18:35:03
User entered '27 Aug 2020 13:34'	System	27 Aug 2020 18:35:03

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 13:18'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 15:48'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:15', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '160ea556-f393-427a-b276-c6a4921fd175'	System	27 Aug 2020 23:05:43
User entered 'None (1)'	System	27 Aug 2020 23:05:43

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:31', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '160ea556-f393-427a-b276-c6a4921fd175'	System	27 Aug 2020 23:05:43
User entered 'No (N)'	System	27 Aug 2020 23:05:43

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:34', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '160ea556-f393-427a-b276-c6a4921fd175'	System	27 Aug 2020 23:05:43
User entered 'No (N)'	System	27 Aug 2020 23:05:43

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:36', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '160ea556-f393-427a-b276-c6a4921fd175'	System	27 Aug 2020 23:05:43
User entered 'None (1)'	System	27 Aug 2020 23:05:43

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:40', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '160ea556-f393-427a-b276-c6a4921fd175'	System	27 Aug 2020 23:05:43
User entered '27 Aug 2020 18:05'	System	27 Aug 2020 23:05:43

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 16:43'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 2'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:54:34', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '37b72b3c-bf35-47e3-8d31-4b7598a008f8'	System	28 Aug 2020 21:55:06
User entered 'None (1)'	System	28 Aug 2020 21:55:06

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:54:40', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '37b72b3c-bf35-47e3-8d31-4b7598a008f8'	System	28 Aug 2020 21:55:06
User entered 'No (N)'	System	28 Aug 2020 21:55:06

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:54:44', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '37b72b3c-bf35-47e3-8d31-4b7598a008f8'	System	28 Aug 2020 21:55:06
User entered 'No (N)'	System	28 Aug 2020 21:55:06

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:54:57', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '37b72b3c-bf35-47e3-8d31-4b7598a008f8'	System	28 Aug 2020 21:55:06
User entered 'None (1)'	System	28 Aug 2020 21:55:06

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:55:00', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '37b72b3c-bf35-47e3-8d31-4b7598a008f8'	System	28 Aug 2020 21:55:06
User entered '28 Aug 2020 16:55'	System	28 Aug 2020 21:55:06

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 3'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:30', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '39112f98-6b5d-49eb-a101-0050f34c93b6'	System	29 Aug 2020 17:59:48
User entered 'None (1)'	System	29 Aug 2020 17:59:48

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:33', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '39112f98-6b5d-49eb-a101-0050f34c93b6'	System	29 Aug 2020 17:59:48
User entered 'No (N)'	System	29 Aug 2020 17:59:48

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:35', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '39112f98-6b5d-49eb-a101-0050f34c93b6'	System	29 Aug 2020 17:59:48
User entered 'No (N)'	System	29 Aug 2020 17:59:48

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:44', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '39112f98-6b5d-49eb-a101-0050f34c93b6'	System	29 Aug 2020 17:59:48
User entered 'None (1)'	System	29 Aug 2020 17:59:48

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:46', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '39112f98-6b5d-49eb-a101-0050f34c93b6'	System	29 Aug 2020 17:59:48
User entered '29 Aug 2020 12:59'	System	29 Aug 2020 17:59:48

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 4'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:48:54', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a5b32574-4934-4120-9168-8414a3196193'	System	30 Aug 2020 20:49:42
User entered 'None (1)'	System	30 Aug 2020 20:49:42

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:49:19', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a5b32574-4934-4120-9168-8414a3196193'	System	30 Aug 2020 20:49:42
User entered 'No (N)'	System	30 Aug 2020 20:49:42

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:49:22', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a5b32574-4934-4120-9168-8414a3196193'	System	30 Aug 2020 20:49:42
User entered 'No (N)'	System	30 Aug 2020 20:49:42

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:49:33', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a5b32574-4934-4120-9168-8414a3196193'	System	30 Aug 2020 20:49:42
User entered 'None (1)'	System	30 Aug 2020 20:49:42

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:49:40', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a5b32574-4934-4120-9168-8414a3196193'	System	30 Aug 2020 20:49:42
User entered '30 Aug 2020 15:49'	System	30 Aug 2020 20:49:42

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 5'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:25', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f618b832-94e7-41ea-8c9c-2ba8d56a8e9e'	System	01 Sep 2020 05:46:37
User entered 'None (1)'	System	01 Sep 2020 05:46:37

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:27', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f618b832-94e7-41ea-8c9c-2ba8d56a8e9e'	System	01 Sep 2020 05:46:37
User entered 'No (N)'	System	01 Sep 2020 05:46:37

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:29', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f618b832-94e7-41ea-8c9c-2ba8d56a8e9e'	System	01 Sep 2020 05:46:37
User entered 'No (N)'	System	01 Sep 2020 05:46:37

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:31', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f618b832-94e7-41ea-8c9c-2ba8d56a8e9e'	System	01 Sep 2020 05:46:37
User entered 'None (1)'	System	01 Sep 2020 05:46:37

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:34', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f618b832-94e7-41ea-8c9c-2ba8d56a8e9e'	System	01 Sep 2020 05:46:37
User entered '01 Sep 2020 00:46'	System	01 Sep 2020 05:46:37

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 6'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:48:06', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b56a7a24-460c-40e4-885a-18966f5113aa'	System	01 Sep 2020 21:48:43
User entered 'None (1)'	System	01 Sep 2020 21:48:43

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:48:26', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b56a7a24-460c-40e4-885a-18966f5113aa'	System	01 Sep 2020 21:48:43
User entered 'No (N)'	System	01 Sep 2020 21:48:43

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:48:29', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b56a7a24-460c-40e4-885a-18966f5113aa'	System	01 Sep 2020 21:48:43
User entered 'No (N)'	System	01 Sep 2020 21:48:43

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:48:39', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b56a7a24-460c-40e4-885a-18966f5113aa'	System	01 Sep 2020 21:48:43
User entered 'None (1)'	System	01 Sep 2020 21:48:43

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:48:42', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b56a7a24-460c-40e4-885a-18966f5113aa'	System	01 Sep 2020 21:48:43
User entered '01 Sep 2020 16:48'	System	01 Sep 2020 21:48:43

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 7'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:24', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ad265e51-3191-4394-b2f1-047426a79690'	System	02 Sep 2020 23:21:51
User entered 'None (1)'	System	02 Sep 2020 23:21:51

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:27', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ad265e51-3191-4394-b2f1-047426a79690'	System	02 Sep 2020 23:21:51
User entered 'No (N)'	System	02 Sep 2020 23:21:51

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:36', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ad265e51-3191-4394-b2f1-047426a79690'	System	02 Sep 2020 23:21:51
User entered 'No (N)'	System	02 Sep 2020 23:21:51

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:45', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ad265e51-3191-4394-b2f1-047426a79690'	System	02 Sep 2020 23:21:51
User entered 'None (1)'	System	02 Sep 2020 23:21:51

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:48', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ad265e51-3191-4394-b2f1-047426a79690'	System	02 Sep 2020 23:21:51
User entered '02 Sep 2020 18:21'	System	02 Sep 2020 23:21:51

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:35:13', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b3982c62-440e-4566-ac72-84704eb6e874'	System	27 Aug 2020 18:36:20
User entered 'None (0)'	System	27 Aug 2020 18:36:20

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:35:18', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b3982c62-440e-4566-ac72-84704eb6e874'	System	27 Aug 2020 18:36:20
User entered 'None (0)'	System	27 Aug 2020 18:36:20

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:35:49', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b3982c62-440e-4566-ac72-84704eb6e874'	System	27 Aug 2020 18:36:20
User entered 'None (0)'	System	27 Aug 2020 18:36:20

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:35:52', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b3982c62-440e-4566-ac72-84704eb6e874'	System	27 Aug 2020 18:36:20
User entered 'None (0)'	System	27 Aug 2020 18:36:20

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:35:55', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b3982c62-440e-4566-ac72-84704eb6e874'	System	27 Aug 2020 18:36:20
User entered 'None (0)'	System	27 Aug 2020 18:36:20

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:36:03', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b3982c62-440e-4566-ac72-84704eb6e874'	System	27 Aug 2020 18:36:20
User entered 'None (0)'	System	27 Aug 2020 18:36:20

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:36:07', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b3982c62-440e-4566-ac72-84704eb6e874'	System	27 Aug 2020 18:36:20
User entered 'No (N)'	System	27 Aug 2020 18:36:20

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T13:36:18', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b3982c62-440e-4566-ac72-84704eb6e874'	System	27 Aug 2020 18:36:20
User entered '27 Aug 2020 13:36'	System	27 Aug 2020 18:36:20

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 13:18'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 15:48'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:43', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a2bba691-6f99-4f04-926f-8edd3c3c61bb'	System	27 Aug 2020 23:06:00
User entered 'None (0)'	System	27 Aug 2020 23:06:00

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:45', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a2bba691-6f99-4f04-926f-8edd3c3c61bb'	System	27 Aug 2020 23:06:00
User entered 'None (0)'	System	27 Aug 2020 23:06:00

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:46', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a2bba691-6f99-4f04-926f-8edd3c3c61bb'	System	27 Aug 2020 23:06:00
User entered 'None (0)'	System	27 Aug 2020 23:06:00

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:47', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a2bba691-6f99-4f04-926f-8edd3c3c61bb'	System	27 Aug 2020 23:06:00
User entered 'None (0)'	System	27 Aug 2020 23:06:00

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:49', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a2bba691-6f99-4f04-926f-8edd3c3c61bb'	System	27 Aug 2020 23:06:00
User entered 'None (0)'	System	27 Aug 2020 23:06:00

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:50', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a2bba691-6f99-4f04-926f-8edd3c3c61bb'	System	27 Aug 2020 23:06:00
User entered 'None (0)'	System	27 Aug 2020 23:06:00

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:54', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a2bba691-6f99-4f04-926f-8edd3c3c61bb'	System	27 Aug 2020 23:06:00
User entered 'No (N)'	System	27 Aug 2020 23:06:00

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-27T18:05:56', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a2bba691-6f99-4f04-926f-8edd3c3c61bb'	System	27 Aug 2020 23:06:00
User entered '27 Aug 2020 18:05'	System	27 Aug 2020 23:06:00

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 16:43'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 2'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:56:56', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '67253877-8ed7-4daa-b13e-6bfc913cf751'	System	28 Aug 2020 21:57:39
User entered 'None (0)'	System	28 Aug 2020 21:57:39

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:56:58', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '67253877-8ed7-4daa-b13e-6bfc913cf751'	System	28 Aug 2020 21:57:39
User entered 'None (0)'	System	28 Aug 2020 21:57:39

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:56:59', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '67253877-8ed7-4daa-b13e-6bfc913cf751'	System	28 Aug 2020 21:57:39
User entered 'None (0)'	System	28 Aug 2020 21:57:39

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:57:01', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '67253877-8ed7-4daa-b13e-6bfc913cf751'	System	28 Aug 2020 21:57:39
User entered 'None (0)'	System	28 Aug 2020 21:57:39

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:57:02', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '67253877-8ed7-4daa-b13e-6bfc913cf751'	System	28 Aug 2020 21:57:39
User entered 'None (0)'	System	28 Aug 2020 21:57:39

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:57:04', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '67253877-8ed7-4daa-b13e-6bfc913cf751'	System	28 Aug 2020 21:57:39
User entered 'None (0)'	System	28 Aug 2020 21:57:39

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:57:06', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '67253877-8ed7-4daa-b13e-6bfc913cf751'	System	28 Aug 2020 21:57:39
User entered 'No (N)'	System	28 Aug 2020 21:57:39

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-28T16:57:35', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '67253877-8ed7-4daa-b13e-6bfc913cf751'	System	28 Aug 2020 21:57:39
User entered '28 Aug 2020 16:57'	System	28 Aug 2020 21:57:39

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 3'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:48', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ef1bb2ce-5741-46d0-8115-dc6c516bf2f8'	System	29 Aug 2020 18:00:06
User entered 'None (0)'	System	29 Aug 2020 18:00:06

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:50', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ef1bb2ce-5741-46d0-8115-dc6c516bf2f8'	System	29 Aug 2020 18:00:06
User entered 'None (0)'	System	29 Aug 2020 18:00:06

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:51', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ef1bb2ce-5741-46d0-8115-dc6c516bf2f8'	System	29 Aug 2020 18:00:06
User entered 'None (0)'	System	29 Aug 2020 18:00:06

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:52', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ef1bb2ce-5741-46d0-8115-dc6c516bf2f8'	System	29 Aug 2020 18:00:06
User entered 'None (0)'	System	29 Aug 2020 18:00:06

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:53', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ef1bb2ce-5741-46d0-8115-dc6c516bf2f8'	System	29 Aug 2020 18:00:06
User entered 'None (0)'	System	29 Aug 2020 18:00:06

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:55', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ef1bb2ce-5741-46d0-8115-dc6c516bf2f8'	System	29 Aug 2020 18:00:06
User entered 'None (0)'	System	29 Aug 2020 18:00:06

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T12:59:58', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ef1bb2ce-5741-46d0-8115-dc6c516bf2f8'	System	29 Aug 2020 18:00:06
User entered 'No (N)'	System	29 Aug 2020 18:00:06

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-29T13:00:00', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'ef1bb2ce-5741-46d0-8115-dc6c516bf2f8'	System	29 Aug 2020 18:00:06
User entered '29 Aug 2020 13:00'	System	29 Aug 2020 18:00:06

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 4'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:49:43', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'dbb32368-05bb-4403-8960-ea21a929e0f8'	System	30 Aug 2020 20:50:07
User entered 'None (0)'	System	30 Aug 2020 20:50:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:49:44', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'dbb32368-05bb-4403-8960-ea21a929e0f8'	System	30 Aug 2020 20:50:07
User entered 'None (0)'	System	30 Aug 2020 20:50:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:49:46', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'dbb32368-05bb-4403-8960-ea21a929e0f8'	System	30 Aug 2020 20:50:07
User entered 'None (0)'	System	30 Aug 2020 20:50:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:49:48', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'dbb32368-05bb-4403-8960-ea21a929e0f8'	System	30 Aug 2020 20:50:07
User entered 'None (0)'	System	30 Aug 2020 20:50:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:49:50', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'dbb32368-05bb-4403-8960-ea21a929e0f8'	System	30 Aug 2020 20:50:07
User entered 'None (0)'	System	30 Aug 2020 20:50:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:49:54', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'dbb32368-05bb-4403-8960-ea21a929e0f8'	System	30 Aug 2020 20:50:07
User entered 'None (0)'	System	30 Aug 2020 20:50:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:49:57', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'dbb32368-05bb-4403-8960-ea21a929e0f8'	System	30 Aug 2020 20:50:07
User entered 'No (N)'	System	30 Aug 2020 20:50:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-08-30T15:50:02', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'dbb32368-05bb-4403-8960-ea21a929e0f8'	System	30 Aug 2020 20:50:07
User entered '30 Aug 2020 15:50'	System	30 Aug 2020 20:50:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 5'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:38', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f69b3965-b703-475a-915b-e05c03bd1d3a'	System	01 Sep 2020 05:46:50
User entered 'None (0)'	System	01 Sep 2020 05:46:50

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:39', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f69b3965-b703-475a-915b-e05c03bd1d3a'	System	01 Sep 2020 05:46:50
User entered 'None (0)'	System	01 Sep 2020 05:46:50

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:41', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f69b3965-b703-475a-915b-e05c03bd1d3a'	System	01 Sep 2020 05:46:50
User entered 'None (0)'	System	01 Sep 2020 05:46:50

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:42', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f69b3965-b703-475a-915b-e05c03bd1d3a'	System	01 Sep 2020 05:46:50
User entered 'None (0)'	System	01 Sep 2020 05:46:50

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:43', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f69b3965-b703-475a-915b-e05c03bd1d3a'	System	01 Sep 2020 05:46:50
User entered 'None (0)'	System	01 Sep 2020 05:46:50

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:45', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f69b3965-b703-475a-915b-e05c03bd1d3a'	System	01 Sep 2020 05:46:50
User entered 'None (0)'	System	01 Sep 2020 05:46:50

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:47', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f69b3965-b703-475a-915b-e05c03bd1d3a'	System	01 Sep 2020 05:46:50
User entered 'No (N)'	System	01 Sep 2020 05:46:50

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T00:46:49', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f69b3965-b703-475a-915b-e05c03bd1d3a'	System	01 Sep 2020 05:46:50
User entered '01 Sep 2020 00:46'	System	01 Sep 2020 05:46:50

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 6'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:48:45', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a3313b8e-d038-44d6-b594-ada4aa14883e' User entered 'None (0)'	System	01 Sep 2020 21:49:19
	System	01 Sep 2020 21:49:19

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:48:47', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a3313b8e-d038-44d6-b594-ada4aa14883e' User entered 'None (0)'	System	01 Sep 2020 21:49:19
	System	01 Sep 2020 21:49:19

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:48:48', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a3313b8e-d038-44d6-b594-ada4aa14883e' User entered 'None (0)'	System	01 Sep 2020 21:49:19
	System	01 Sep 2020 21:49:19

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:48:49', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a3313b8e-d038-44d6-b594-ada4aa14883e' User entered 'None (0)'	System	01 Sep 2020 21:49:19
	System	01 Sep 2020 21:49:19

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:49:10', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a3313b8e-d038-44d6-b594-ada4aa14883e'	System	01 Sep 2020 21:49:19
User entered 'None (0)'	System	01 Sep 2020 21:49:19

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:49:13', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a3313b8e-d038-44d6-b594-ada4aa14883e' User entered 'None (0)'	System	01 Sep 2020 21:49:19
	System	01 Sep 2020 21:49:19

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:49:15', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a3313b8e-d038-44d6-b594-ada4aa14883e'	System	01 Sep 2020 21:49:19
User entered 'No (N)'	System	01 Sep 2020 21:49:19

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-01T16:49:17', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a3313b8e-d038-44d6-b594-ada4aa14883e'	System	01 Sep 2020 21:49:19
User entered '01 Sep 2020 16:49'	System	01 Sep 2020 21:49:19

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 7'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:51', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f01e06d4-055a-4f0a-be09-a66f56f75d1b'	System	02 Sep 2020 23:22:07
User entered 'None (0)'	System	02 Sep 2020 23:22:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:53', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f01e06d4-055a-4f0a-be09-a66f56f75d1b'	System	02 Sep 2020 23:22:07
User entered 'None (0)'	System	02 Sep 2020 23:22:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:54', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f01e06d4-055a-4f0a-be09-a66f56f75d1b'	System	02 Sep 2020 23:22:07
User entered 'None (0)'	System	02 Sep 2020 23:22:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:55', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f01e06d4-055a-4f0a-be09-a66f56f75d1b' User entered 'None (0)'	System	02 Sep 2020 23:22:07
	System	02 Sep 2020 23:22:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:56', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f01e06d4-055a-4f0a-be09-a66f56f75d1b'	System	02 Sep 2020 23:22:07
User entered 'None (0)'	System	02 Sep 2020 23:22:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:21:58', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f01e06d4-055a-4f0a-be09-a66f56f75d1b'	System	02 Sep 2020 23:22:07
User entered 'None (0)'	System	02 Sep 2020 23:22:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:22:00', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f01e06d4-055a-4f0a-be09-a66f56f75d1b'	System	02 Sep 2020 23:22:07
User entered 'No (N)'	System	02 Sep 2020 23:22:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-02T18:22:03', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f01e06d4-055a-4f0a-be09-a66f56f75d1b'	System	02 Sep 2020 23:22:07
User entered '02 Sep 2020 18:22'	System	02 Sep 2020 23:22:07

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 18:09:13

US3812280

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 19:56:09

US3812280

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '04 Sep 2020' reason for change: Per Query Resolution	Karen Knapp (b) (4)	10 Nov 2020 23:09:41
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 19:56:09

US3812280

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Sep 2020 19:56:09

US3812280

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:56:09

US3812280

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	10 Sep 2020 18:39:41

US3812280

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 18:39:41

US3812280

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	10 Sep 2020 18:39:51

US3812280

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Karen Knapp (b) (4) (b) (4)	10 Sep 2020 18:39:51

US3812280

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	10 Sep 2020 18:39:51

US3812280

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	10 Sep 2020 18:39:51

US3812280

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	10 Sep 2020 18:39:55

US3812280

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 18:39:55

US3812280

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	17 Sep 2020 17:35:27

US3812280

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Karen Knapp (b) (4) (b) (4)	17 Sep 2020 17:35:27

US3812280

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	17 Sep 2020 17:35:27

US3812280

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	17 Sep 2020 17:35:27

US3812280

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	17 Sep 2020 17:35:32

US3812280

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:35:32

US3812280

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Sep 2020 19:46:16

US3812280

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	24 Sep 2020 19:46:16

US3812280

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	24 Sep 2020 19:46:16

US3812280

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	24 Sep 2020 19:46:16

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 17:19:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 17:19:32
User entered '13:37' reason for change: Data Entry Error	Breanna Galibert (b) (4)	30 Sep 2020 17:19:32
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 17:18:59
User entered empty.	Breanna Galibert (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '24 Sep 2020 13:37'	System	30 Sep 2020 17:19:32
User entered empty.	System	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 17:19:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 17:19:32
User entered '97.3' F reason for change: Per Query Resolution	Breanna Galibert (b) (4)	30 Sep 2020 17:19:32
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 17:18:59
User entered empty.	Breanna Galibert (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	30 Sep 2020 17:19:32
User entered empty.	Breanna Galibert (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 17:19:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 17:19:32
User entered '92' reason for change: Data Entry Error	Breanna Galibert (b) (4)	30 Sep 2020 17:19:32
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 17:18:59
User entered empty.	Breanna Galibert (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 17:19:32
User entered empty.	System	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 17:19:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 17:19:32
User entered '16' reason for change: Data Entry Error	Breanna Galibert (b) (4)	30 Sep 2020 17:19:32
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 17:18:59
User entered empty.	Breanna Galibert (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 17:19:32
User entered empty.	System	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 17:19:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 17:19:32
User entered '102' reason for change: Data Entry Error	Breanna Galibert (b) (4)	30 Sep 2020 17:19:32
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 17:18:59
User entered empty.	Breanna Galibert (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 17:19:32
User entered empty.	System	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 17:19:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 17:19:32
User entered '78' reason for change: Data Entry Error	Breanna Galibert (b) (4)	30 Sep 2020 17:19:32
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 17:18:59
User entered empty.	Breanna Galibert (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:56:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 17:19:32
User entered empty.	System	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '14:53'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:53'	System	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '98'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '14'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '82'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:56:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 17:18:59

US3812280

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:17:38

US3812280

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:17:38

US3812280

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

Was the pregnancy test performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:17:54

US3812280

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:17:54

US3812280

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:17:54

US3812280

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:17:54

US3812280

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:17:54

US3812280

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:17:54

US3812280

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:17:54

US3812280

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:17:54

US3812280

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Sep 2020 19:46:31

US3812280

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Sep 2020 19:46:31

US3812280

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Sep 2020 19:46:31

US3812280

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 19:46:31

US3812280

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	24 Sep 2020 19:46:31

US3812280

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:15'	Breanna Galibert (b) (4) (b) (4)	24 Sep 2020 19:46:31

US3812280

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:15'	System	24 Sep 2020 19:46:31

US3812280

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4) (b) (4)	24 Sep 2020 19:46:31

US3812280

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	24 Sep 2020 19:46:31

US3812280

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:56:03

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 19:46:31

US3812280

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:07

US3812280

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:07

US3812280

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:00'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:07

US3812280

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:00'	System	30 Sep 2020 17:18:07

US3812280

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:56:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:26

US3812280

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:56:03

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4)	30 Sep 2020 17:18:26

US3812280

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:56:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:26

US3812280

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:56:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:05'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:26

US3812280

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:05'	System	30 Sep 2020 17:18:26

US3812280

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:56:03

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4)	30 Sep 2020 17:18:26

US3812280

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:56:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:26

US3812280

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:56:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 17:18:26

US3812280

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:18:26

US3812280

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	01 Oct 2020 20:44:00

US3812280

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:44:00

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:48:53', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'd6a51521-3f67-41fe-9990-6e50529e2f28'	System	24 Sep 2020 19:49:06
User entered 'Yes (Y)'	System	24 Sep 2020 19:49:06

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:48:57', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'd6a51521-3f67-41fe-9990-6e50529e2f28'	System	24 Sep 2020 19:49:06
User entered '98.0'	System	24 Sep 2020 19:49:06

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:49:00', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'd6a51521-3f67-41fe-9990-6e50529e2f28'	System	24 Sep 2020 19:49:06
User entered 'No (N)'	System	24 Sep 2020 19:49:06

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:49:02', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'd6a51521-3f67-41fe-9990-6e50529e2f28'	System	24 Sep 2020 19:49:06
User entered '24 Sep 2020 14:49'	System	24 Sep 2020 19:49:06

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:35'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 17:05'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:29:25', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '702504ae-d9c6-4f9c-8d64-f1bfaac00f8e'	System	25 Sep 2020 03:29:36
User entered 'Yes (Y)'	System	25 Sep 2020 03:29:36

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:29:29', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '702504ae-d9c6-4f9c-8d64-f1bfaac00f8e' User entered '97.6'	System	25 Sep 2020 03:29:36

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:29:31', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '702504ae-d9c6-4f9c-8d64-f1bfaac00f8e'	System	25 Sep 2020 03:29:36
User entered 'No (N)'	System	25 Sep 2020 03:29:36

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:29:33', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '702504ae-d9c6-4f9c-8d64-f1bfaac00f8e'	System	25 Sep 2020 03:29:36
User entered '24 Sep 2020 22:29'	System	25 Sep 2020 03:29:36

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 18:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 2'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:19:09', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '6a8e86ce-a2ed-45b5-8089-00436a0e8795'	System	25 Sep 2020 20:19:26
User entered 'Yes (Y)'	System	25 Sep 2020 20:19:26

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:19:13', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '6a8e86ce-a2ed-45b5-8089-00436a0e8795'	System	25 Sep 2020 20:19:26
User entered '97.9'	System	25 Sep 2020 20:19:26

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:19:16', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '6a8e86ce-a2ed-45b5-8089-00436a0e8795'	System	25 Sep 2020 20:19:26
User entered 'Yes (Y)'	System	25 Sep 2020 20:19:26

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 15:22:07
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED' (Site from System).	Angie Kean (b) (4)	07 Oct 2020 13:46:18
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:19:20', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '6a8e86ce-a2ed-45b5-8089-00436a0e8795'	System	25 Sep 2020 20:19:26
User entered '1'	System	25 Sep 2020 20:19:26

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:19:20', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '6a8e86ce-a2ed-45b5-8089-00436a0e8795'	System	25 Sep 2020 20:19:26
User entered '0'	System	25 Sep 2020 20:19:26

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:19:23', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '6a8e86ce-a2ed-45b5-8089-00436a0e8795'	System	25 Sep 2020 20:19:26
User entered '25 Sep 2020 15:19'	System	25 Sep 2020 20:19:26

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 3'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:12', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '581a0f9d-05bc-40dd-bd21-0ffaccb622d1'	System	26 Sep 2020 18:22:24
User entered 'Yes (Y)'	System	26 Sep 2020 18:22:24

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:17', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '581a0f9d-05bc-40dd-bd21-0ffaccb622d1'	System	26 Sep 2020 18:22:24
User entered '99.2'	System	26 Sep 2020 18:22:24

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:19', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '581a0f9d-05bc-40dd-bd21-0ffaccb622d1'	System	26 Sep 2020 18:22:24
User entered 'No (N)'	System	26 Sep 2020 18:22:24

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:22', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '581a0f9d-05bc-40dd-bd21-0ffaccb622d1'	System	26 Sep 2020 18:22:24
User entered '26 Sep 2020 13:22'	System	26 Sep 2020 18:22:24

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 4'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:59', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '367f82ee-24ba-491b-8531-b0bc96c94dca' User entered 'Yes (Y)'	System	28 Sep 2020 05:01:32
	System	28 Sep 2020 05:01:32

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T00:01:25', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '367f82ee-24ba-491b-8531-b0bc96c94dca' User entered '97.5'	System	28 Sep 2020 05:01:32
	System	28 Sep 2020 05:01:32

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T00:01:27', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '367f82ee-24ba-491b-8531-b0bc96c94dca'	System	28 Sep 2020 05:01:32
User entered 'No (N)'	System	28 Sep 2020 05:01:32

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T00:01:29', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '367f82ee-24ba-491b-8531-b0bc96c94dca' User entered '28 Sep 2020 00:01'	System	28 Sep 2020 05:01:32
	System	28 Sep 2020 05:01:32

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 5'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:24:59', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '5a70bc58-aaf5-4da8-a7b9-0a5553adddb1' User entered 'Yes (Y)'	System	28 Sep 2020 19:25:08
	System	28 Sep 2020 19:25:08

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:03', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '5a70bc58-aaf5-4da8-a7b9-0a5553adddb1' User entered '98.5'	System	28 Sep 2020 19:25:08
	System	28 Sep 2020 19:25:08

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:04', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '5a70bc58-aaf5-4da8-a7b9-0a5553adddb1'	System	28 Sep 2020 19:25:08
User entered 'No (N)'	System	28 Sep 2020 19:25:08

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:06', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '5a70bc58-aaf5-4da8-a7b9-0a5553adddb1' User entered '28 Sep 2020 14:25'	System	28 Sep 2020 19:25:08
	System	28 Sep 2020 19:25:08

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 6'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:42:36', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'c0567b31-d152-4488-9494-630c3487a131'	System	29 Sep 2020 23:42:48
User entered 'Yes (Y)'	System	29 Sep 2020 23:42:48

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:42:39', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'c0567b31-d152-4488-9494-630c3487a131'	System	29 Sep 2020 23:42:48
User entered '98.5'	System	29 Sep 2020 23:42:48

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:42:42', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'c0567b31-d152-4488-9494-630c3487a131'	System	29 Sep 2020 23:42:48
User entered 'No (N)'	System	29 Sep 2020 23:42:48

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:42:43', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'c0567b31-d152-4488-9494-630c3487a131'	System	29 Sep 2020 23:42:48
User entered '29 Sep 2020 18:42'	System	29 Sep 2020 23:42:48

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 7'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:43:01', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '73ead936-05b5-440b-b5a4-7de32042988c'	System	01 Oct 2020 13:44:19
User entered 'Yes (Y)'	System	01 Oct 2020 13:44:19

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:09', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '73ead936-05b5-440b-b5a4-7de32042988c' User entered '98.8'	System	01 Oct 2020 13:44:19

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:15', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '73ead936-05b5-440b-b5a4-7de32042988c'	System	01 Oct 2020 13:44:19
User entered 'No (N)'	System	01 Oct 2020 13:44:19

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:18', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '73ead936-05b5-440b-b5a4-7de32042988c' User entered '01 Oct 2020 08:44'	System	01 Oct 2020 13:44:19
	System	01 Oct 2020 13:44:19

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:49:14', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '8d0792aa-9b77-498a-9770-2eac8f9fc379'	System	24 Sep 2020 19:49:52
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 19:49:52

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:49:30', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '8d0792aa-9b77-498a-9770-2eac8f9fc379'	System	24 Sep 2020 19:49:52
User entered 'No (N)'	System	24 Sep 2020 19:49:52

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:49:40', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '8d0792aa-9b77-498a-9770-2eac8f9fc379'	System	24 Sep 2020 19:49:52
User entered 'No (N)'	System	24 Sep 2020 19:49:52

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:49:47', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '8d0792aa-9b77-498a-9770-2eac8f9fc379'	System	24 Sep 2020 19:49:52
User entered 'None (1)'	System	24 Sep 2020 19:49:52

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:49:49', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '8d0792aa-9b77-498a-9770-2eac8f9fc379'	System	24 Sep 2020 19:49:52
User entered '24 Sep 2020 14:49'	System	24 Sep 2020 19:49:52

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:35'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 17:05'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:27:00', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '5ec99159-7773-474b-9d32-d3cf6661ecc0'	System	25 Sep 2020 03:27:18
User entered 'None (1)'	System	25 Sep 2020 03:27:18

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:27:02', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '5ec99159-7773-474b-9d32-d3cf6661ecc0'	System	25 Sep 2020 03:27:18
User entered 'No (N)'	System	25 Sep 2020 03:27:18

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:27:04', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '5ec99159-7773-474b-9d32-d3cf6661ecc0'	System	25 Sep 2020 03:27:18
User entered 'No (N)'	System	25 Sep 2020 03:27:18

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:27:13', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '5ec99159-7773-474b-9d32-d3cf6661ecc0'	System	25 Sep 2020 03:27:18
User entered 'None (1)'	System	25 Sep 2020 03:27:18

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:27:16', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '5ec99159-7773-474b-9d32-d3cf6661ecc0'	System	25 Sep 2020 03:27:18
User entered '24 Sep 2020 22:27'	System	25 Sep 2020 03:27:18

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 18:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 2'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:19:29', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '15c0cea6-3519-4f0e-be72-785518af6971'	System	25 Sep 2020 20:19:54
User entered 'None (1)'	System	25 Sep 2020 20:19:54

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:19:41', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '15c0cea6-3519-4f0e-be72-785518af6971'	System	25 Sep 2020 20:19:54
User entered 'No (N)'	System	25 Sep 2020 20:19:54

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:19:44', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '15c0cea6-3519-4f0e-be72-785518af6971'	System	25 Sep 2020 20:19:54
User entered 'No (N)'	System	25 Sep 2020 20:19:54

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:19:49', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '15c0cea6-3519-4f0e-be72-785518af6971'	System	25 Sep 2020 20:19:54
User entered 'None (1)'	System	25 Sep 2020 20:19:54

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:19:50', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '15c0cea6-3519-4f0e-be72-785518af6971'	System	25 Sep 2020 20:19:54
User entered '25 Sep 2020 15:19'	System	25 Sep 2020 20:19:54

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 3'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:35', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '1ea4ccca-6719-413f-a630-42deb5ca3112'	System	26 Sep 2020 18:22:49
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 18:22:49

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:34', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '1ea4ccca-6719-413f-a630-42deb5ca3112'	System	26 Sep 2020 18:22:49
User entered 'No (N)'	System	26 Sep 2020 18:22:49

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:37', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '1ea4ccca-6719-413f-a630-42deb5ca3112'	System	26 Sep 2020 18:22:49
User entered 'No (N)'	System	26 Sep 2020 18:22:49

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:39', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '1ea4ccca-6719-413f-a630-42deb5ca3112'	System	26 Sep 2020 18:22:49
User entered 'None (1)'	System	26 Sep 2020 18:22:49

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:44', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '1ea4ccca-6719-413f-a630-42deb5ca3112'	System	26 Sep 2020 18:22:49
User entered '26 Sep 2020 13:22'	System	26 Sep 2020 18:22:49

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 4'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:22', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '536c4fc4-4c3c-47d5-85f0-664346e7fc49'	System	28 Sep 2020 04:59:31
User entered 'None (1)'	System	28 Sep 2020 04:59:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:23', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '536c4fc4-4c3c-47d5-85f0-664346e7fc49'	System	28 Sep 2020 04:59:31
User entered 'No (N)'	System	28 Sep 2020 04:59:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:25', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '536c4fc4-4c3c-47d5-85f0-664346e7fc49'	System	28 Sep 2020 04:59:31
User entered 'No (N)'	System	28 Sep 2020 04:59:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:26', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '536c4fc4-4c3c-47d5-85f0-664346e7fc49'	System	28 Sep 2020 04:59:31
User entered 'None (1)'	System	28 Sep 2020 04:59:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:28', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '536c4fc4-4c3c-47d5-85f0-664346e7fc49'	System	28 Sep 2020 04:59:31
User entered '27 Sep 2020 23:59'	System	28 Sep 2020 04:59:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 5'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:13', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '9b338c2c-b5da-4767-9a4f-65ed88acdf08'	System	28 Sep 2020 19:25:26
User entered 'None (1)'	System	28 Sep 2020 19:25:26

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:15', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '9b338c2c-b5da-4767-9a4f-65ed88acdf08'	System	28 Sep 2020 19:25:26
User entered 'No (N)'	System	28 Sep 2020 19:25:26

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:16', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '9b338c2c-b5da-4767-9a4f-65ed88acdf08'	System	28 Sep 2020 19:25:26
User entered 'No (N)'	System	28 Sep 2020 19:25:26

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:18', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '9b338c2c-b5da-4767-9a4f-65ed88acdf08'	System	28 Sep 2020 19:25:26
User entered 'None (1)'	System	28 Sep 2020 19:25:26

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:24', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '9b338c2c-b5da-4767-9a4f-65ed88acdf08'	System	28 Sep 2020 19:25:26
User entered '28 Sep 2020 14:25'	System	28 Sep 2020 19:25:26

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 6'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:42:46', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f1d79b29-5874-450d-89d0-3ac2c00e7f4b'	System	29 Sep 2020 23:43:01
User entered 'None (1)'	System	29 Sep 2020 23:43:01

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:42:48', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f1d79b29-5874-450d-89d0-3ac2c00e7f4b'	System	29 Sep 2020 23:43:01
User entered 'No (N)'	System	29 Sep 2020 23:43:01

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:42:52', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f1d79b29-5874-450d-89d0-3ac2c00e7f4b'	System	29 Sep 2020 23:43:01
User entered 'No (N)'	System	29 Sep 2020 23:43:01

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:42:56', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f1d79b29-5874-450d-89d0-3ac2c00e7f4b'	System	29 Sep 2020 23:43:01
User entered 'None (1)'	System	29 Sep 2020 23:43:01

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:42:58', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'f1d79b29-5874-450d-89d0-3ac2c00e7f4b'	System	29 Sep 2020 23:43:01
User entered '29 Sep 2020 18:42'	System	29 Sep 2020 23:43:01

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 7'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:20', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'dbc7876d-06b7-4f43-93a3-d359abb66d62'	System	01 Oct 2020 13:44:30
User entered 'None (1)'	System	01 Oct 2020 13:44:30

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:22', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'dbc7876d-06b7-4f43-93a3-d359abb66d62'	System	01 Oct 2020 13:44:30
User entered 'No (N)'	System	01 Oct 2020 13:44:30

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:24', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'dbc7876d-06b7-4f43-93a3-d359abb66d62'	System	01 Oct 2020 13:44:30
User entered 'No (N)'	System	01 Oct 2020 13:44:30

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:25', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'dbc7876d-06b7-4f43-93a3-d359abb66d62'	System	01 Oct 2020 13:44:30
User entered 'None (1)'	System	01 Oct 2020 13:44:30

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:27', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'dbc7876d-06b7-4f43-93a3-d359abb66d62'	System	01 Oct 2020 13:44:30
User entered '01 Oct 2020 08:44'	System	01 Oct 2020 13:44:30

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:49:52', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'c7041dc6-4eff-42a8-ad87-8cdc5ec078f3'	System	24 Sep 2020 19:51:07
User entered 'None (0)'	System	24 Sep 2020 19:51:07

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:50:18', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'c7041dc6-4eff-42a8-ad87-8cdc5ec078f3'	System	24 Sep 2020 19:51:07
User entered 'No interference with activity (1)'	System	24 Sep 2020 19:51:07

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:50:22', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'c7041dc6-4eff-42a8-ad87-8cdc5ec078f3'	System	24 Sep 2020 19:51:07
User entered 'None (0)'	System	24 Sep 2020 19:51:07

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:50:24', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'c7041dc6-4eff-42a8-ad87-8cdc5ec078f3' User entered 'None (0)'	System	24 Sep 2020 19:51:07
	System	24 Sep 2020 19:51:07

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:50:27', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'c7041dc6-4eff-42a8-ad87-8cdc5ec078f3'	System	24 Sep 2020 19:51:07
User entered 'None (0)'	System	24 Sep 2020 19:51:07

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:50:56', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'c7041dc6-4eff-42a8-ad87-8cdc5ec078f3'	System	24 Sep 2020 19:51:07
User entered 'No interference with activity (1)'	System	24 Sep 2020 19:51:07

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:51:01', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'c7041dc6-4eff-42a8-ad87-8cdc5ec078f3'	System	24 Sep 2020 19:51:07
User entered 'No (N)'	System	24 Sep 2020 19:51:07

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T14:51:03', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'c7041dc6-4eff-42a8-ad87-8cdc5ec078f3' User entered '24 Sep 2020 14:51'	System	24 Sep 2020 19:51:07
	System	24 Sep 2020 19:51:07

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:35'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 17:05'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:27:19', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b4755488-9e1b-4f90-970e-6810cbd0ef08'	System	25 Sep 2020 03:27:36
User entered 'None (0)'	System	25 Sep 2020 03:27:36

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:27:24', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b4755488-9e1b-4f90-970e-6810cbd0ef08'	System	25 Sep 2020 03:27:36
User entered 'None (0)'	System	25 Sep 2020 03:27:36

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:27:25', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b4755488-9e1b-4f90-970e-6810cbd0ef08'	System	25 Sep 2020 03:27:36
User entered 'None (0)'	System	25 Sep 2020 03:27:36

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:27:26', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b4755488-9e1b-4f90-970e-6810cbd0ef08'	System	25 Sep 2020 03:27:36
User entered 'None (0)'	System	25 Sep 2020 03:27:36

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:27:28', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b4755488-9e1b-4f90-970e-6810cbd0ef08'	System	25 Sep 2020 03:27:36
User entered 'None (0)'	System	25 Sep 2020 03:27:36

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:27:29', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b4755488-9e1b-4f90-970e-6810cbd0ef08'	System	25 Sep 2020 03:27:36
User entered 'None (0)'	System	25 Sep 2020 03:27:36

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:27:33', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b4755488-9e1b-4f90-970e-6810cbd0ef08'	System	25 Sep 2020 03:27:36
User entered 'No (N)'	System	25 Sep 2020 03:27:36

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-24T22:27:34', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b4755488-9e1b-4f90-970e-6810cbd0ef08'	System	25 Sep 2020 03:27:36
User entered '24 Sep 2020 22:27'	System	25 Sep 2020 03:27:36

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 18:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 2'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:20:01', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '20f97ee5-1a3c-4619-b84e-7ea8eb97b013'	System	25 Sep 2020 20:20:21
User entered 'No interference with activity (1)'	System	25 Sep 2020 20:20:21

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:20:06', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '20f97ee5-1a3c-4619-b84e-7ea8eb97b013'	System	25 Sep 2020 20:20:21
User entered 'None (0)'	System	25 Sep 2020 20:20:21

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:20:08', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '20f97ee5-1a3c-4619-b84e-7ea8eb97b013'	System	25 Sep 2020 20:20:21
User entered 'None (0)'	System	25 Sep 2020 20:20:21

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:20:09', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '20f97ee5-1a3c-4619-b84e-7ea8eb97b013'	System	25 Sep 2020 20:20:21
User entered 'None (0)'	System	25 Sep 2020 20:20:21

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:20:10', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '20f97ee5-1a3c-4619-b84e-7ea8eb97b013'	System	25 Sep 2020 20:20:21
User entered 'None (0)'	System	25 Sep 2020 20:20:21

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:20:13', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '20f97ee5-1a3c-4619-b84e-7ea8eb97b013'	System	25 Sep 2020 20:20:21
User entered 'No interference with activity (1)'	System	25 Sep 2020 20:20:21

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:20:16', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '20f97ee5-1a3c-4619-b84e-7ea8eb97b013'	System	25 Sep 2020 20:20:21
User entered 'No (N)'	System	25 Sep 2020 20:20:21

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-25T15:20:18', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '20f97ee5-1a3c-4619-b84e-7ea8eb97b013'	System	25 Sep 2020 20:20:21
User entered '25 Sep 2020 15:20'	System	25 Sep 2020 20:20:21

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 3'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:47', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'e0d1a66a-68a3-4f98-a38e-4e460e3252a4'	System	26 Sep 2020 18:23:01
User entered 'None (0)'	System	26 Sep 2020 18:23:01

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:49', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'e0d1a66a-68a3-4f98-a38e-4e460e3252a4'	System	26 Sep 2020 18:23:01
User entered 'None (0)'	System	26 Sep 2020 18:23:01

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:50', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'e0d1a66a-68a3-4f98-a38e-4e460e3252a4'	System	26 Sep 2020 18:23:01
User entered 'None (0)'	System	26 Sep 2020 18:23:01

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:52', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'e0d1a66a-68a3-4f98-a38e-4e460e3252a4'	System	26 Sep 2020 18:23:01
User entered 'None (0)'	System	26 Sep 2020 18:23:01

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:54', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'e0d1a66a-68a3-4f98-a38e-4e460e3252a4'	System	26 Sep 2020 18:23:01
User entered 'None (0)'	System	26 Sep 2020 18:23:01

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:55', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'e0d1a66a-68a3-4f98-a38e-4e460e3252a4'	System	26 Sep 2020 18:23:01
User entered 'None (0)'	System	26 Sep 2020 18:23:01

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:57', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'e0d1a66a-68a3-4f98-a38e-4e460e3252a4'	System	26 Sep 2020 18:23:01
User entered 'No (N)'	System	26 Sep 2020 18:23:01

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-26T13:22:59', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'e0d1a66a-68a3-4f98-a38e-4e460e3252a4'	System	26 Sep 2020 18:23:01
User entered '26 Sep 2020 13:22'	System	26 Sep 2020 18:23:01

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 4'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:32', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a966e010-8abd-43be-b3bd-d3f15441950a'	System	28 Sep 2020 04:59:55
User entered 'None (0)'	System	28 Sep 2020 04:59:55

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:36', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a966e010-8abd-43be-b3bd-d3f15441950a'	System	28 Sep 2020 04:59:55
User entered 'None (0)'	System	28 Sep 2020 04:59:55

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:39', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a966e010-8abd-43be-b3bd-d3f15441950a' User entered 'None (0)'	System	28 Sep 2020 04:59:55
	System	28 Sep 2020 04:59:55

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:44', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a966e010-8abd-43be-b3bd-d3f15441950a' User entered 'None (0)'	System	28 Sep 2020 04:59:55
	System	28 Sep 2020 04:59:55

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:46', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a966e010-8abd-43be-b3bd-d3f15441950a' User entered 'None (0)'	System	28 Sep 2020 04:59:55
	System	28 Sep 2020 04:59:55

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:48', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a966e010-8abd-43be-b3bd-d3f15441950a'	System	28 Sep 2020 04:59:55
User entered 'None (0)'	System	28 Sep 2020 04:59:55

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:50', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a966e010-8abd-43be-b3bd-d3f15441950a'	System	28 Sep 2020 04:59:55
User entered 'No (N)'	System	28 Sep 2020 04:59:55

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-27T23:59:52', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'a966e010-8abd-43be-b3bd-d3f15441950a'	System	28 Sep 2020 04:59:55
User entered '27 Sep 2020 23:59'	System	28 Sep 2020 04:59:55

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 5'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:27', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '68e3e013-c77a-48f5-8131-546efad65fde' User entered 'None (0)'	System	28 Sep 2020 19:25:41

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:28', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '68e3e013-c77a-48f5-8131-546efad65fde' User entered 'None (0)'	System	28 Sep 2020 19:25:41
	System	28 Sep 2020 19:25:41

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:29', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '68e3e013-c77a-48f5-8131-546efad65fde' User entered 'None (0)'	System	28 Sep 2020 19:25:41
	System	28 Sep 2020 19:25:41

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:31', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '68e3e013-c77a-48f5-8131-546efad65fde' User entered 'None (0)'	System	28 Sep 2020 19:25:41
	System	28 Sep 2020 19:25:41

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:32', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '68e3e013-c77a-48f5-8131-546efad65fde' User entered 'None (0)'	System	28 Sep 2020 19:25:41

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:34', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '68e3e013-c77a-48f5-8131-546efad65fde' User entered 'None (0)'	System	28 Sep 2020 19:25:41
	System	28 Sep 2020 19:25:41

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:35', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '68e3e013-c77a-48f5-8131-546efad65fde' User entered 'No (N)'	System	28 Sep 2020 19:25:41

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-28T14:25:37', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '68e3e013-c77a-48f5-8131-546efad65fde' User entered '28 Sep 2020 14:25'	System	28 Sep 2020 19:25:41
	System	28 Sep 2020 19:25:41

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 6'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:43:06', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '42ffaada-e5a2-49df-899d-2bce8a5b6272'	System	29 Sep 2020 23:43:20
User entered 'None (0)'	System	29 Sep 2020 23:43:20

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:43:07', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '42ffaana-e5a2-49df-899d-2bce8a5b6272'	System	29 Sep 2020 23:43:20
User entered 'None (0)'	System	29 Sep 2020 23:43:20

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:43:09', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '42ffaada-e5a2-49df-899d-2bce8a5b6272'	System	29 Sep 2020 23:43:20
User entered 'None (0)'	System	29 Sep 2020 23:43:20

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:43:10', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '42ffaada-e5a2-49df-899d-2bce8a5b6272'	System	29 Sep 2020 23:43:20
User entered 'None (0)'	System	29 Sep 2020 23:43:20

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:43:11', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '42ffaaaa-e5a2-49df-899d-2bce8a5b6272'	System	29 Sep 2020 23:43:20
User entered 'None (0)'	System	29 Sep 2020 23:43:20

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:43:13', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '42ffaada-e5a2-49df-899d-2bce8a5b6272'	System	29 Sep 2020 23:43:20
User entered 'None (0)'	System	29 Sep 2020 23:43:20

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:43:15', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '42ffaada-e5a2-49df-899d-2bce8a5b6272'	System	29 Sep 2020 23:43:20
User entered 'No (N)'	System	29 Sep 2020 23:43:20

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-09-29T18:43:18', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '42ffaaaa-e5a2-49df-899d-2bce8a5b6272'	System	29 Sep 2020 23:43:20
User entered '29 Sep 2020 18:43'	System	29 Sep 2020 23:43:20

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 19:46:31
User entered 'Day 7'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:30', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b014ac78-2d41-474a-ae52-397f52425027'	System	01 Oct 2020 13:44:43
User entered 'None (0)'	System	01 Oct 2020 13:44:43

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:31', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b014ac78-2d41-474a-ae52-397f52425027'	System	01 Oct 2020 13:44:43
User entered 'None (0)'	System	01 Oct 2020 13:44:43

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:33', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b014ac78-2d41-474a-ae52-397f52425027'	System	01 Oct 2020 13:44:43
User entered 'None (0)'	System	01 Oct 2020 13:44:43

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:34', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b014ac78-2d41-474a-ae52-397f52425027'	System	01 Oct 2020 13:44:43
User entered 'None (0)'	System	01 Oct 2020 13:44:43

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:36', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b014ac78-2d41-474a-ae52-397f52425027'	System	01 Oct 2020 13:44:43
User entered 'None (0)'	System	01 Oct 2020 13:44:43

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:37', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b014ac78-2d41-474a-ae52-397f52425027'	System	01 Oct 2020 13:44:43
User entered 'None (0)'	System	01 Oct 2020 13:44:43

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:39', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b014ac78-2d41-474a-ae52-397f52425027'	System	01 Oct 2020 13:44:43
User entered 'No (N)'	System	01 Oct 2020 13:44:43

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-01T08:44:40', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'b014ac78-2d41-474a-ae52-397f52425027' User entered '01 Oct 2020 08:44'	System	01 Oct 2020 13:44:43
	System	01 Oct 2020 13:44:43

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 19:46:31

US3812280

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:56:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 19:46:31

US3812280

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	01 Oct 2020 20:44:12

US3812280

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '1 Oct 2020'	Karen Knapp (b) (4) (b) (4)	01 Oct 2020 20:44:12

US3812280

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	01 Oct 2020 20:44:12

US3812280

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	01 Oct 2020 20:44:12

US3812280

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	01 Oct 2020 20:44:18

US3812280

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:44:18

US3812280

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	08 Oct 2020 21:32:09

US3812280

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Karen Knapp (b) (4) (b) (4)	08 Oct 2020 21:32:09

US3812280

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	08 Oct 2020 21:32:09

US3812280

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	08 Oct 2020 21:32:09

US3812280

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	08 Oct 2020 21:32:13

US3812280

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 21:32:13

US3812280

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	15 Oct 2020 17:31:39

US3812280

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Karen Knapp (b) (4) (b) (4)	15 Oct 2020 17:31:39

US3812280

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	15 Oct 2020 17:31:39

US3812280

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	15 Oct 2020 17:31:39

US3812280

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	15 Oct 2020 17:31:43

US3812280

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:31:43

US3812280

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:18

US3812280

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:18

US3812280

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:18

US3812280

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	29 Oct 2020 22:11:18

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '14:20'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '29 Oct 2020 14:20'	System	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.5' F	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Pulse (xxx)

Audit	User	Time (GMT)
User entered '93'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '17'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '108'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Oct 2020 22:11:38

US3812280

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:48

US3812280

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:48

US3812280

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 29OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' answered with 'Please review as GCL portal shows samples received' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 29OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM). User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	13 Nov 2020 20:08:16
	(b) (4), (b) (6)	06 Nov 2020 17:39:36
	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:57

US3812280

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:57

US3812280

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:30'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:11:57

US3812280

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '29 Oct 2020 14:30'	System	29 Oct 2020 22:11:57

US3812280

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:12:34

US3812280

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 22:12:34

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 64'	System	27 Aug 2020 18:09:13

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-27T13:45:31', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'e9beeff5-979b-4244-a41b-bc2b5bb0f3ee'	System	27 Oct 2020 18:46:29
User entered 'Yes (Y)'	System	27 Oct 2020 18:46:29

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

Have you been exposed to someone with 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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-27T13:45:34', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'e9beeff5-979b-4244-a41b-bc2b5bb0f3ee'	System	27 Oct 2020 18:46:29
User entered 'No (N)'	System	27 Oct 2020 18:46:29

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-27T13:45:56', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'e9beeff5-979b-4244-a41b-bc2b5bb0f3ee' User entered 'No (N)'	System	27 Oct 2020 18:46:29
	System	27 Oct 2020 18:46:29

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-27T13:46:18', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'e9beeff5-979b-4244-a41b-bc2b5bb0f3ee' User entered 'No (N)'	System	27 Oct 2020 18:46:29
	System	27 Oct 2020 18:46:29

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-10-27T13:46:26', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'e9beeff5-979b-4244-a41b-bc2b5bb0f3ee' User entered '27 Oct 2020 13:46:26'	System	27 Oct 2020 18:46:29
	System	27 Oct 2020 18:46:29

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 18:09:13

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 71'	System	27 Aug 2020 18:09:13

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-11-03T18:45:00', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '644391d4-0b26-4a9b-ba3d-fa3d6431c682'	System	04 Nov 2020 00:45:10
User entered 'No (N)'	System	04 Nov 2020 00:45:10

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Have you been exposed to someone with 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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-11-03T18:45:05', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '644391d4-0b26-4a9b-ba3d-fa3d6431c682'	System	04 Nov 2020 00:45:10
User entered 'No (N)'	System	04 Nov 2020 00:45:10

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-11-03T18:45:08', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '644391d4-0b26-4a9b-ba3d-fa3d6431c682'	System	04 Nov 2020 00:45:10
User entered '03 Nov 2020 18:45:08'	System	04 Nov 2020 00:45:10

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 18:09:13

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered 'Day 78'	System	27 Aug 2020 18:09:13

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-11-10T22:42:24', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '596662cf-212b-4664-96a2-e1f72f88328c'	System	11 Nov 2020 04:42:42
User entered 'No (N)'	System	11 Nov 2020 04:42:42

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Have you been exposed to someone with 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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-11-10T22:42:36', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '596662cf-212b-4664-96a2-e1f72f88328c'	System	11 Nov 2020 04:42:42
User entered 'No (N)'	System	11 Nov 2020 04:42:42

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-11-10T22:42:40', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: '596662cf-212b-4664-96a2-e1f72f88328c' User entered '10 Nov 2020 22:42:40'	System	11 Nov 2020 04:42:42
	System	11 Nov 2020 04:42:42

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 18:09:13

US3812280

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 18:09:13
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 18:09:13

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '24 Oct 2020 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '28 Oct 2020 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '31 Oct 2020 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '04 Nov 2020 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '07 Nov 2020 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '11 Nov 2020 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '14 Nov 2020 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '18 Nov 2020 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-11-23T15:21:24', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'fdf1eb18-541a-4309-be90-6eec7ccbdad9'	System	23 Nov 2020 21:21:31
User entered 'No (N)'	System	23 Nov 2020 21:21:31

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Have you been exposed to someone with 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 (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-11-23T15:21:26', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'fdf1eb18-541a-4309-be90-6eec7ccbdad9'	System	23 Nov 2020 21:21:31
User entered 'No (N)'	System	23 Nov 2020 21:21:31

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8F15FF8-C882-4E22-B4FC-E7761B300C0A)', Time: '2020-11-23T15:21:28', User OID: 'PatientReportedOutcome (US3812280)', ODM File OID: 'fdf1eb18-541a-4309-be90-6eec7ccbdad9' User entered '23 Nov 2020 15:21:28'	System	23 Nov 2020 21:21:31
	System	23 Nov 2020 21:21:31

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 19:05:25

US3812280

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:56:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:05:25
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 19:05:25

US3812280

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	18 Nov 2020 20:29:32

US3812280

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Karen Knapp (b) (4) (b) (4)	18 Nov 2020 20:29:32

US3812280

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	18 Nov 2020 20:29:32

US3812280

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:56:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	18 Nov 2020 20:29:32

US3812280

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	18 Nov 2020 20:29:36

US3812280

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:56:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 20:29:36

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:56:03

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:55:17
User entered '19 Nov 2020'	Breanna Galibert (b) (4)	19 Nov 2020 23:17:52

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:56:03

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:55:17
User entered '13:40'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:17:52

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:56:03

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 13:40'	System	19 Nov 2020 23:17:52

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:56:03

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:55:17
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:17:52

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:56:03

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:55:17
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:17:52

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '13 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '1'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:20:43
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:20:43
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:20:43
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:20:43
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:20:43

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:20:43
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '14 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '1'	Breanna Galibert (b) (4)	19 Nov 2020 23:21:06
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:21:06

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:21:06
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:21:06
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:21:06
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:21:06
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:21:06
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:06

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '15 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '1'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:21:22

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:21:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:21:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:21:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:22

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:21:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '16 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '1'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:21:49
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:21:49
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:21:49

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '17 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '1'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:22:15

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:22:15
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:22:15
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:22:15
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:22:15
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:15

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '18 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '1'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:22:48
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:22:48
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:22:48
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:22:48
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:22:48
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:22:48
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:22:48
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:22:48

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
Query 'Please reconcile and enter days since 19Nov20. As a reminder symptom log is to be entered within 24 hrs of daily illness call completion' canceled (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:20:06
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User opened query 'Please reconcile and enter days since 19Nov20. As a reminder symptom log is to be entered within 24 hrs of daily illness call completion' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 16:26:01
User entered '19 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '0'	Breanna Galibert (b) (4)	19 Nov 2020 23:23:18
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '99'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered '98.7' F	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:23:18
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Nov 2020 23:23:18
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:39
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:23:18

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:23

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:07
User entered '20 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:23

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:09
User entered '0'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:23
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:11
User entered '100'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:23

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 15:38:23

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:12
User entered '97.8' F	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:23

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:29
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:23

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:20
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:23

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:22
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:23

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:27
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:23
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:25
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:23

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:32
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:23
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:39
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:23
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:40
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:23
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:42
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:23

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:53
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:23
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:44
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:23
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:52
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:23
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:50
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:23

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:08:58
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:23

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:09:00
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:23

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:09:04
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:23

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:51

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:14
User entered '21 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:51

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:13
User entered '0'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:51
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:11
User entered '98'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:51
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 15:38:51

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:10
User entered '98.1' F	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:51

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:17
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:51

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:22
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:51

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:24
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:51

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:30
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:51

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:28
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:51

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:32
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:51

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:36
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:51
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:38
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:51

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:40
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:51

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:42
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:51
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:48
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:51
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:47
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:51
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:45
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:51

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:49
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:51
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:52
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:38:51
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:07:51
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:38:51

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:39:30

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:36
User entered '22 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:39:30

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:38
User entered '0'	Breanna Galibert (b) (4)	24 Nov 2020 15:39:30
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:41
User entered '100'	Breanna Galibert (b) (4)	24 Nov 2020 15:39:30
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 15:39:30

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:42
User entered '99.3' F	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:39:30

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:50
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:39:30

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:52
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:39:30

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:55
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:39:30

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:58
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:39:30

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:06:15
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:39:30

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:06:14
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:39:30
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:06:12
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:39:30
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:06:10
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:39:30

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:06:17
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:39:30

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:06:19
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:39:30
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:06:28
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:39:30
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:06:27
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:39:30
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:06:25
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:39:30

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:06:33
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:39:30

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:06:31
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:39:30

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:06:35
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:39:30
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:04:20
User entered '23 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:04:23
User entered '0'	Breanna Galibert (b) (4)	24 Nov 2020 15:40:04
	(b) (4)	

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:04:26
User entered '99'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 15:40:04

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:04:28
User entered '98.7' F	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:04:32
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:04:40
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:04:45
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:04:47
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:04:50
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:04:51
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:04:54
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:04:57
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:10
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:12
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:40:04
	(b) (4)	

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:15
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:40:04
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:16
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:40:04
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:17
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:40:04
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:19
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:21
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:04

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:05:23
User entered 'None (None)'	Breanna Galibert (b) (4)	24 Nov 2020 15:40:04
	(b) (4)	

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Form: COVID Diagnostic Test

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[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:56
User entered '19 Nov 2020' reason for change: Data Entry Error	Angie Kean (b) (4)	23 Nov 2020 19:43:44
User entered '13 Nov 2020'	Breanna Galibert (b) (4)	19 Nov 2020 23:24:02

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:24:02

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:17:51
User closed query 'Please confirm test result was positive. Update AE if needed.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 16:25:28
Query 'Please confirm test result was positive. Update AE if needed.' answered with 'UPDATED' (Site from CRA).	Angie Kean (b) (4)	24 Nov 2020 16:19:34
User opened query 'Please confirm test result was positive. Update AE if needed.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:16:06
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 15:44:21
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'ADDED TO AE FORM' (Site from System).	Breanna Galibert (b) (4)	19 Nov 2020 23:37:34
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	19 Nov 2020 23:24:02
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Nov 2020 23:24:02

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
User closed query 'Per source date of local COVID test is 13Nov20. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:30:02
Query 'Per source date of local COVID test is 13Nov20. Please confirm with source and update accordingly.' answered with 'source was updated to reflect this change' (Site from CRA).	Lyly Dang (b) (4)	24 Nov 2020 19:42:19
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:17:45
User opened query 'Per source date of local COVID test is 13Nov20. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:17:32
User entered '14 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	24 Nov 2020 16:46:23
DataPoint Un-verified.	Angie Kean (b) (4)	24 Nov 2020 16:19:24
User entered '13 Nov 2020' reason for change: Data Entry Error	Angie Kean (b) (4)	24 Nov 2020 16:19:24
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:00:04
User entered '19 Nov 2020' reason for change: Data Entry Error	Angie Kean (b) (4)	23 Nov 2020 19:43:44
User entered '13 Nov 2020'	Breanna Galibert (b) (4)	19 Nov 2020 23:24:02

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

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[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:00:05
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Breanna Galibert (b) (4)	19 Nov 2020 23:24:02

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:00:07
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:24:02

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:17:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	24 Nov 2020 16:19:24
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	23 Nov 2020 23:00:55
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	23 Nov 2020 19:43:44
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	23 Nov 2020 19:43:44
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:24:02

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:17:38
User entered 'SLU HOSPITAL' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	24 Nov 2020 16:19:24
User closed query 'Please provide full name of lab/institution' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:18:12
Query 'Please provide full name of lab/institution' answered with 'updated' (Site from CRA).	Angie Kean (b) (4) (b) (4)	23 Nov 2020 19:43:54
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	23 Nov 2020 19:43:44
User opened query 'Please provide full name of lab/institution' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 20:23:05
User entered 'SUI ED'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:24:02

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:17:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Angie Kean (b) (4)	24 Nov 2020 16:19:24
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	23 Nov 2020 23:00:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Nov 2020 23:24:02

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 23:24:02

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Form: Covid-19 Severity Assessment

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Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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Did the subject have Heart Rate $\geq$ 125 beats per minute

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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Form: Covid-19 Severity Assessment

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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Form: Covid-19 Severity Assessment

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:56:03

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:50
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:34:00

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:56:03

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:07:16

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:56:03

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '13:30'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:07:16

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:56:03

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 13:30'	System	23 Oct 2020 15:07:16

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:56:03

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Breanna Galibert (b) (4)	23 Oct 2020 15:07:16

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:56:03

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:07:16

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:08:09

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:09:34

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:10

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:10:55

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:11:35

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:12:13

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.0' F	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:13:46

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.1' F	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:19:25

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.9' F	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:20:32

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Date](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	27 Oct 2020 14:33:32
User entered '24 Oct 2020'	Breanna Galibert (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.5' F	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:56:03

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:27:14

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:33:12

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:33:12

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:33:12

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

[Date of Test](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:33:12

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

Type of Test Performed

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (NasopharyngealBreanna Galibert Swab)'	(b) (4)	23 Oct 2020 15:33:12

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:33:12

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:33:12

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:33:12

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 15:33:12

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:56:03

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 15:33:12

US3812280

Folder: Covid-19 Assessment 22 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:56:03

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	29 Oct 2020 22:13:34

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:34:12

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:56:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:56:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:40:44

US3812280

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:28:19

US3812280

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:28:19

US3812280

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:28:19

US3812280

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	26 Oct 2020 21:28:19

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '14:13'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '22 Oct 2020 14:13'	System	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Height (xxx.x)

Audit	User	Time (GMT)
User entered '67.0' in	Breanna Galibert (b) (4)	26 Oct 2020 21:29:03
DataPoint set to visible.	(b) (4) System	26 Oct 2020 21:28:19

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '204.0' lb	Breanna Galibert (b) (4)	26 Oct 2020 21:29:03
DataPoint set to visible.	(b) (4) System	26 Oct 2020 21:28:19

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Pulse (xxx)

Audit	User	Time (GMT)
User entered '90'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '16'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '110'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '74'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Oct 2020 21:29:03

US3812280

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:11

US3812280

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:11

US3812280

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:56:03

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:33

US3812280

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 21:29:33

US3812280

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:01:46
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:58:29

US3812280

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:01:46
User entered '19 Nov 2020'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:58:29

US3812280

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:01:46
User entered 'Clinic (Clinic)'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:58:29

US3812280

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:56:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	19 Nov 2020 20:58:29

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:15
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:15
User entered '19 Nov 2020'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:15
User entered '14:23'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '19 Nov 2020 14:23'	System	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:15
User entered '67.0' in	Angie Kean (b) (4)	19 Nov 2020 20:59:15
DataPoint set to visible.	(b) (4) System	19 Nov 2020 20:58:29

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:15
User entered '195.8' lb	Angie Kean (b) (4)	19 Nov 2020 20:59:15
DataPoint set to visible.	(b) (4) System	19 Nov 2020 20:58:29

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:15
User entered '98.7' F	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:15
User entered 'Oral (Oral)'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:15
User entered empty.	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:15
User entered '112'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:15
User entered '16'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:15
User entered '102'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:15
User entered '80'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:56:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 20:59:15

US3812280

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:23
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:29

US3812280

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:56:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:02:23
User entered '19 Nov 2020'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:29

US3812280

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:56:03

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:05:49
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:38

US3812280

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:56:03

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:05:49
User entered '19 Nov 2020'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 20:59:38

US3812280

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:56:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:33:10
User entered 'Yes (Y)' reason for change: New Information	Breanna Galibert (b) (4)	23 Oct 2020 18:39:32
User entered 'No (N)'	Karen Knapp (b) (4)	03 Sep 2020 17:33:04

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Adverse event](#)

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: Esophageal reflux aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 22:12:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 22:12:36
Data point term sent to Coder	System	23 Oct 2020 18:40:35
User entered 'GERD EXACERBATION '	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[None](#)

Audit	User	Time (GMT)
User entered '1'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:56:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 18:40:25

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:42:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:42:39
Data point term sent to Coder	System	23 Oct 2020 18:41:38
User entered 'URINARY TRACT INFECTION'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	29 Oct 2020 22:15:14
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Oct 2020' reason for change: New Information	Breanna Galibert (b) (4)	29 Oct 2020 22:15:14
User entered empty.	Breanna Galibert (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[None](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Breanna Galibert (b) (4)	29 Oct 2020 22:15:14
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Breanna Galibert (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:56:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 18:41:19

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 18:43:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 18:43:41
Data point term sent to Coder	System	23 Oct 2020 18:42:39
User entered 'WORSENING DEPRESSION'	Breanna Galibert (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	29 Oct 2020 22:14:16
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Oct 2020' reason for change: New Information	Breanna Galibert (b) (4)	29 Oct 2020 22:14:16
User entered empty.	Breanna Galibert (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[None](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Breanna Galibert (b) (4)	29 Oct 2020 22:14:16
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Breanna Galibert (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:56:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 18:41:58

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:47
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:04
User entered 'USA-US111-2020-mRNA-1273-P301000009'	System	17 Nov 2020 14:48:49
User entered 'New'	(b) (4), (b) (6)	17 Nov 2020 14:48:49

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:49
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 01:17:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	17 Nov 2020 01:17:50
Data point term sent to Coder	System	17 Nov 2020 01:17:22
User entered 'Worsening Depression'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:51
User entered 'Yes (Y)'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:53
User entered 'No (N)'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:55
User entered 'No (N)'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:57
User entered '12 Nov 2020'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:58
User entered empty.	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:01
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 21:03:34
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4)	19 Nov 2020 21:03:34
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	19 Nov 2020 21:03:15
User entered 'Yes (Y)'	System	19 Nov 2020 21:03:15
	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:05
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	19 Nov 2020 21:03:15
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	19 Nov 2020 21:03:15
User entered '17 Nov 2020' reason for change: New Information	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:03:15
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	19 Nov 2020 21:01:46
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Nov 2020 01:17:09
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	17 Nov 2020 01:17:09
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Nov 2020 01:16:52
User entered empty.	Lyly Dang (b) (4) (b) (4) (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:30
User entered empty.	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:28
User entered 'Grade 4 (Grade 4)'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:26
User entered 'Yes (Y)'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:36
User entered '0'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:34
User entered '0'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:32
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 15:06:33
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).	Lyly Dang (b) (4)	17 Nov 2020 01:17:22
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	17 Nov 2020 01:16:25
User entered '1'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:38
User entered '13 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	17 Nov 2020 01:16:52
User entered empty.	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:40
User closed query 'Per CDM: Please review and update the "Hospital Discharge Date" once available. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 15:45:04
Query 'Per CDM: Please review and update the "Hospital Discharge Date" once available. Thank you.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4)	19 Nov 2020 21:03:42
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 21:01:46
User opened query 'Per CDM: Please review and update the "Hospital Discharge Date" once available. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:06:37
User entered empty.	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:43
User entered 'No (N)'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:44
User entered empty.	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:46
User entered '0'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:48
User entered '0'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:50
User entered '0'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:27:24
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:27:03
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:27:26
User entered 'Not Applicable (NOT APPLICABLE)'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:27:36
User entered '0'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:27:34
User entered '1'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:27:38
User entered '0'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:27:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:01:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Lyly Dang (b) (4)	17 Nov 2020 01:17:09
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 01:16:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 01:16:52
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	Lyly Dang (b) (4)	17 Nov 2020 01:16:52
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 01:16:25
User entered empty.	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:27:42
User entered empty.	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:28:17
User entered 'This is a 30-year-old female who was hospitalized on 13 November 2020 with an admitting diagnosis of "Major Depressive Disorder with Suicidal Ideation." Per medical records, the subject had planned to (b) (6) (b) (6) The subject has a history of anxiety, depression, recurrent suicidal ideation, non-command auditory hallucinations, and chronic fatigue. Pertinent labs include a negative urine drug screen and a positive COVID-19 rapid test. Two subsequent COVID-19 antibody tests were negative. Medical records did not notate what medications were taken by the subject during this hospitalization. Subject was discharged in stable condition on 17 November 2020 and was advised to follow up with psychiatry in one month. The subject was discharged with the following medications: Aripiprazole 2 mg once daily, Bupropion XL 300 mg q HS, Acetaminophen 650 mg q 4 hrs PRN, and Calcium Carbonate 1 g q 4 hrs PRN.' reason for change: Data Entry Error	Lyly Dang (b) (4)	21 Nov 2020 00:32:36
User entered 'SUBJECT CALLED TO NOTIFY SITE THAT SHE HAD A "MENTAL BREAKDOWN LAST WEEK" AND IS CURRENTLY IN THE HOSPITAL FOR WORSENING DEPRESSION. MEDICAL RECORDS WILL BE REQUESTED. NO OTHER INFORMATION REGARDING THE SUBJECT'S MEDICATION OR TREATMENT IS KNOWN AT THIS TIME.' reason for change: Data Entry Error	Lyly Dang (b) (4)	17 Nov 2020 01:17:49
User entered 'Subject called to notify site that she had a "mental breakdown last week" and is currently in the hospital for worsening depression. Medical records will be requested. No other information regarding the subject's medication and treatment is known at this time.'	Lyly Dang (b) (4)	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:56:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 01:16:25

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:05
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:59:02
User entered	(b) (4), (b) (6)	20 Nov 2020 15:58:50
'USA-US111-2020-mRNA-1273-P301000009'		

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:17:41
User closed query 'Per source AE term is noted as symptomatic Covid 19. Please confirm and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:17:39
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:48:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:48:04
Data point term sent to Coder	System	24 Nov 2020 20:47:10
Query 'Per source AE term is noted as symptomatic Covid 19. Please confirm and update accordingly.' answered with 'updated' (Site from CRA).	Lyly Dang (b) (4)	24 Nov 2020 20:46:16
DataPoint Un-verified.	Lyly Dang (b) (4)	24 Nov 2020 20:46:09
Coding entries removed.	Lyly Dang (b) (4)	24 Nov 2020 20:46:09
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Lyly Dang (b) (4)	24 Nov 2020 20:46:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:09
User opened query 'Per source AE term is noted as symptomatic Covid 19. Please confirm and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:20:56
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:38:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:38:50
Data point term sent to Coder	System	19 Nov 2020 23:37:35
User entered 'COVID-19 INFECTION'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:12
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:19
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:23
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:24
User entered '13 Nov 2020'	Breanna Galibert (b) (4)	19 Nov 2020 23:37:11
	(b) (4)	

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:29
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:43
User entered empty.	Breanna Galibert (b) (4)	19 Nov 2020 23:37:11
	(b) (4)	

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:47
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:58
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:02
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:04
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:06
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:09
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:11
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:13
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:16
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:18
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:30
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:32
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:34
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:40
User entered '1'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:42
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:44
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:49
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'Please confirm date of local lab test. Per source date was 13Nov20. Please update narrative comments if needed or clarify.' canceled (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:30:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:24:44
User opened query 'Please confirm date of local lab test. Per source date was 13Nov20. Please update narrative comments if needed or clarify.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:24:43
User entered 'Subject 2280 had a positive COVID-19Lyly Dang (b) (4) rapid test from a CLIA certified lab on 14 November 2020. Subject was brought in for an illness visit on 19Nov2020 for new COVID-19 related sx and recent exposure to someone who was COVID-19 postive. Central lab results from that illness visit showed a negative COVID PCR swab.' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 16:44:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 23:37:11

US3812280

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:56:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 23:37:11

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:56:03

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:24:59
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:16

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 19:20:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 19:20:38
Data point term sent to Coder	System	29 Aug 2020 19:20:21
User entered 'OMEPRAZOLE'	Karen Knapp (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'GERD'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:19:55

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 19:22:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 19:22:38
Data point term sent to Coder	System	29 Aug 2020 19:21:21
User entered 'WELLBUTRIN XL'	Karen Knapp (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'DEPRESSION'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '150'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Aug 2016'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	23 Oct 2020 18:42:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Oct 2020' reason for change: New Information	Breanna Galibert (b) (4)	23 Oct 2020 18:42:40
User entered empty.	Karen Knapp (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:20:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[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: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 19:22:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 19:22:38
Data point term sent to Coder	System	29 Aug 2020 19:21:21
User entered 'ZYRTEC'	Karen Knapp (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'ENVIRONMENTAL ALLERGIES'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Mar 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	23 Oct 2020 18:42:55
User entered 'Yes (Y)'	Karen Knapp (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Oct 2020' reason for change: New Information	Breanna Galibert (b) (4)	23 Oct 2020 18:42:55
User entered empty.	Karen Knapp (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:21:06

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:31:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:31:50
Data point term sent to Coder	System	29 Aug 2020 19:22:22
User entered 'SPIRENOLACTONE'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'BILATERAL LE SWELLING'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Dec 2019'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:21:49

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 19:23:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 19:23:37
Data point term sent to Coder	System	29 Aug 2020 19:23:22
User entered 'MULTIVITAMIN'	Karen Knapp (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'GENERAL HEALTH'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered 'UN Dec 2019'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:22:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: INTRAUTERINE CONTRACEPTIVE DEVICE, PRODUCTSYNONYM: IUD NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 19:24:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 19:24:38
Data point term sent to Coder	System	29 Aug 2020 19:24:23
User entered 'IUD'	Karen Knapp (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 21:07:15
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	Breanna Galibert (b) (4)	24 Nov 2020 15:42:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	24 Nov 2020 15:42:35
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:34:34
User entered 'No (N)'	Karen Knapp (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'CONTRACEPTION'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 19:24:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 19:24:25
User entered 'Other (OTHER)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:24:25
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 19:23:38
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'UNIT' reason for change: Data Entry Error	Karen Knapp (b) (4)	29 Aug 2020 19:24:25
User entered empty.	Karen Knapp (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review frequency = ONCE, as the medication remains ongoing. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 08:53:27
Query 'Per DM CLR: Please review frequency = ONCE, as the medication remains ongoing. Please confirm and update as appropriate, otherwise clarify.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4)	07 Oct 2020 13:47:42
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4)	07 Oct 2020 13:47:11
User opened query 'Per DM CLR: Please review frequency = ONCE, as the medication remains ongoing. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 10:45:07
User entered 'once (ONCE)'	Karen Knapp (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'ONCE EVERY FIVE YEARS' reason for change: Data Entry Error	Angie Kean (b) (4)	07 Oct 2020 13:47:11
User entered empty.	(b) (4)	
	Karen Knapp (b) (4)	29 Aug 2020 19:23:38
	(b) (4)	

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered 'INTRAUTERINE'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:23:38

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 18:44:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 18:44:30
Data point term sent to Coder	System	23 Oct 2020 18:43:40
User entered 'WELLBUTRIN XL'	Breanna Galibert (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'DEPRESSION'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 18:43:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 18:46:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 18:46:40
Data point term sent to Coder	System	23 Oct 2020 18:45:44
User entered 'VITAMIN C'	Breanna Galibert (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'GENERAL HEALTH'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'IU (IU)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 18:45:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 18:47:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 18:47:45
Data point term sent to Coder	System	23 Oct 2020 18:46:48
User entered 'VITAMIN D3'	Breanna Galibert (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'GENERAL HEALTH'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 18:46:32

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[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: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 18:48:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 18:48:33
Data point term sent to Coder	System	23 Oct 2020 18:47:49
User entered 'ZYRTEC'	Breanna Galibert (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'ENVIRONMENTAL ALLERGIES'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 18:47:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
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)	23 Oct 2020 19:43:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:43:36
Data point term sent to Coder	System	23 Oct 2020 19:42:31
User entered 'ibuprofen'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'fever'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:41:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:43:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:43:36
Data point term sent to Coder	System	23 Oct 2020 19:42:32
User entered 'naproxen'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'fever'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '250'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:42:08

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:43:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:43:36
Data point term sent to Coder	System	23 Oct 2020 19:42:33
User entered 'ibuprofen'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'headache'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:42:29

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:44:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:44:39
Data point term sent to Coder	System	23 Oct 2020 19:43:34
User entered 'ibuprofen'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'sore throat'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:42:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 14:36:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 14:36:34
Data point term sent to Coder	System	27 Oct 2020 14:35:42
User entered 'EXCEDRIN'	Breanna Galibert (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'HEADACHE'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 14:35:28

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 14:37:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 14:37:34
Data point term sent to Coder	System	27 Oct 2020 14:36:44
User entered 'EXCEDRIN'	Breanna Galibert (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'HEADACHE'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '25 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 14:35:53

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'CEPACOL LOZENGE' reason for change: New Information	Angie Kean (b) (4)	24 Nov 2020 17:52:31
Data point term sent to Coder	(b) (4)	
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	24 Nov 2020 17:51:40
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'UPDATED' (Site from System).	System	24 Nov 2020 17:50:39
Data point term sent to Coder	Angie Kean (b) (4)	24 Nov 2020 17:50:39
User entered 'CEPACOL NUMBING LOZENGE' reason for change: New Information	(b) (4)	
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 14:37:51
Data point term sent to Coder	(b) (4)	
User entered 'NUMBING LOZENGE'	System	27 Oct 2020 14:37:46
	Breanna Galibert (b) (4)	27 Oct 2020 14:37:00
	(b) (4)	

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'SORE THROAT'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '4'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'DOSES'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 14:37:00

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 21:37:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 21:37:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 21:22:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 21:22:17
Data point term sent to Coder User entered 'ABILIFY'	System Angie Kean (b) (4)	19 Nov 2020 21:06:34 19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'MAJOR DEPRESSIVE DISORDER'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 21:06:27

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 15:43:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 15:43:15
Data point term sent to Coder	System	24 Nov 2020 15:42:08
User entered 'ibuprofen'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'headache'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '21 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 15:41:50

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:58
Data point term sent to Coder	System	24 Nov 2020 17:55:46
User entered 'CALCIUM CARBONATE'	Angie Kean (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'GERD'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'g (g)'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 17:55:44

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 18:01:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 18:01:57
Data point term sent to Coder	System	24 Nov 2020 18:00:55
User entered 'ACETAMINOPHEN'	Angie Kean (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'HEADACHES'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '650'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

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

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:56:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:00:21

US3812280

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:56:03

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	03 Sep 2020 17:33:09

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'USA-US111-2020-MRNA-1273-P301000009'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Yes (Y)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Yes (Y)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Larkin'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Wadsworth'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered '711 Old Ballas Rd Suite 105'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'St Louis'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered '63141'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:59:14
User entered 'US'	System	17 Nov 2020 14:49:26

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Nov 2020 21:27:30
User entered '2'	System	20 Nov 2020 15:59:29
User entered '1'	System	17 Nov 2020 14:49:26

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'USA-US111-2020-MRNA-1273-P301000009'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Yes (Y)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Yes (Y)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Larkin'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Wadsworth'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered '711 Old Ballas Rd Suite 105'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'St Louis'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered '63141'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:59:14
User entered 'US'	System	17 Nov 2020 14:49:26

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Nov 2020 21:27:30
User entered '2'	System	20 Nov 2020 15:59:29
User entered '1'	System	17 Nov 2020 14:49:26

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:56:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
User entered '17/Nov/2020 09:49'	System	17 Nov 2020 14:49:26

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:56:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:59:14
User entered '1'	(b) (4), (b) (6)	17 Nov 2020 14:49:26

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'USA-US111-2020-MRNA-1273-P301000009'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Yes (Y)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Yes (Y)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Larkin'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Wadsworth'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered '711 Old Ballas Rd Suite 105'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'St Louis'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered '63141'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:59:14
User entered 'US'	System	17 Nov 2020 14:49:26

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Nov 2020 21:27:30
User entered '2'	System	20 Nov 2020 15:59:29
User entered '1'	System	17 Nov 2020 14:49:26

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:56:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
User entered '20/Nov/2020 10:59'	System	20 Nov 2020 15:59:29

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:56:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:27:13
User entered '1'	(b) (4), (b) (6)	20 Nov 2020 15:59:29

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'USA-US111-2020-MRNA-1273-P301000009'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Yes (Y)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Yes (Y)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'No (N)'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Larkin'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'Wadsworth'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered '711 Old Ballas Rd Suite 105'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered 'St Louis'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:49:18
User entered '63141'	System	17 Nov 2020 14:48:49

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:59:14
User entered 'US'	System	17 Nov 2020 14:49:26

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:56:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Nov 2020 21:27:30
User entered '2'	System	20 Nov 2020 15:59:29
User entered '1'	System	17 Nov 2020 14:49:26

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:56:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
User entered '23/Nov/2020 16:27'	System	23 Nov 2020 21:27:30

US3812280

Folder: SAE USA-US111-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:56:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:43
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 21:27:30