

US3862086 (Prod: Baylor College of Medicine)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:31:55

All time stamps listed in this document are displayed in GMT

US3862086

Form: Participant Creation

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

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Participant ID

US3862086

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

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US3862086

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	28 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3862086

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Date of Birth (MMM yyyy)	(b) (6) 1992
Age	28
Age Units	YEARS
Age (Derived)	28
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	True
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:38:53

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3862086

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:38:53

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	EXERCISE INDUCED ASTHMA
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	ECZEMA
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	ENDOMETRIAL EXCISION
Start date (dd MMM yyyy)	UN JUL 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUL 2017
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JUL 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN AUG 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2015
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2015
Start Year (derived)	2015
Stop Month and Year (derived)	AUG 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	ALLERGY TO RIBAVIRIN
Start date (dd MMM yyyy)	20 MAR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	ALLERGY TO PCN
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Condition	EXPOSURE TO HEPATITIS C
Start date (dd MMM yyyy)	20 MAR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	20 MAR 2019
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	MAR 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	14:08 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 14:08
Height (xxx.x)	065.5 in
Weight (xxx.x)	225.5 lb
BMI (xxx.x)	37.03172 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 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

Data signed: (b) (4) 13 Feb 2021 00:38:52

Generated On: 12 Aug 2021 13:31:55

Date of assessment (dd MMM yyyy) 28 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

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	28 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:38:53

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	28 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 109877

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

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	14:08 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 14:08
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	080 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	082 mmHg
Diastolic Blood Pressure units	MMHG



US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	17:14 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 17:14
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="checkbox"/> Axillary <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If Other, specify	TEMPORAL
Pulse (xxx)	083 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	021 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	083 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

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

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 16:44 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 16:44

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

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

Collection date (dd MMM yyyy)	28 AUG 2020
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Collection time (00:00-23:59)	15:50 (24 HR)
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Collection date and time (derived)	28 AUG 2020 15:50
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:15	28 AUG 2020 15:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

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: 12 Aug 2021 13:31:55

**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

28 AUG 2020 17:15

PC Open Date & Time

28 AUG 2020 17:04

PC Close Date & Time

28 AUG 2020 19:34



US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

**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 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	28 AUG 2020 22:14
PC Open Date & Time	28 AUG 2020 20:29
PC Close Date & Time	29 AUG 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 14:14

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:55

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 21:49

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:55

**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

97.7 °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

31 AUG 2020 17:44

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:55

**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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 22:22

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:55

**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

97.9 °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

02 SEP 2020 22:10

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 21:23

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

**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

28 AUG 2020 17:17

PC Open Date & Time

28 AUG 2020 17:04

PC Close Date & Time

28 AUG 2020 19:34



US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

**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

28 AUG 2020 22:15

PC Open Date & Time

28 AUG 2020 20:29

PC Close Date & Time

29 AUG 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:55

**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

29 AUG 2020 14:14

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:55

**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

30 AUG 2020 21:50

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:55

**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

31 AUG 2020 17:44

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:55

**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 22:22

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:55

**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

02 SEP 2020 22:10

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:55

**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

03 SEP 2020 21:23

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

**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 ☐



US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 17:17
PC Open Date & Time	28 AUG 2020 17:04
PC Close Date & Time	28 AUG 2020 19:34

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

**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 ☐

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 22:15
PC Open Date & Time	28 AUG 2020 20:29
PC Close Date & Time	29 AUG 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:55

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:55

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 14:15
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:55

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:55

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 21:50
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:55

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:55

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 17:44
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:55

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 22:22
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:55

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

67 of 1201

EAB) (1725)

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:55

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

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:55

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 ☒

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:55

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:23
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3862086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:38:52

Generated On: 12 Aug 2021 13:31:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3862086

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:38:52

Generated On: 12 Aug 2021 13:31:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862086

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:38:52

Generated On: 12 Aug 2021 13:31:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862086

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:38:52

Generated On: 12 Aug 2021 13:31:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:38:52

Generated On: 12 Aug 2021 13:31:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862086

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:38:52

Generated On: 12 Aug 2021 13:31:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862086

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	14:14 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 14:14
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

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



US3862086

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3862086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	25 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3862086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Was study treatment given? Yes ☐  
No ☒

If No, reason not given

Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☒  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3862086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

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

Collection date (dd MMM yyyy)	25 SEP 2020
-------------------------------	-------------

Collection time (00:00-23:59)	16:03 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	25 SEP 2020 16:03
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US3862086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	Yes	15:42	25 SEP 2020 15:42

US3862086

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:38:52

Generated On: 12 Aug 2021 13:31:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 OCT 2020

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

Comments DAY 36 CONTACT MADE  
OUTSIDE OF WINDOW.

*If Contact Not Made, please provide Comments*

US3862086

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:38:52

Generated On: 12 Aug 2021 13:31:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3862086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:38:52

Generated On: 12 Aug 2021 13:31:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862086

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:38:52

Generated On: 12 Aug 2021 13:31:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:38:52

Generated On: 12 Aug 2021 13:31:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 OCT 2020

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

Comments CONTACT WAS ATTEMPTED  
ONCE ON 16OCT2020 AND  
If Contact Not Made, please provide Comments TWICE ON 19OCT2020. SUBJECT  
WAS NOT REACHABLE.

US3862086

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:38:52

Generated On: 12 Aug 2021 13:31:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862086

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

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 VISIT3

US3862086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3862086

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

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.*

US3862086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)



US3862086

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:38:53

Generated On: 12 Aug 2021 13:31:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

**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

13 NOV 2020 12:32:58

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

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 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59



US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

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 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 15:30:43
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 18:08:42
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 12:00:15

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 12:09:46
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 08:27:54

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

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 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 JAN 2021 12:00:19

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

**US3862086**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 12 Aug 2021 13:31:55**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

US3862086

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:28:35

Generated On: 12 Aug 2021 13:31:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 NOV 2020

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

Comments TECHNICAL ISSUES WITH  
SUBJECT DEVICE

*If Contact Not Made, please provide Comments*

US3862086

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 14:02:02

Generated On: 12 Aug 2021 13:31:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862086

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 14:02:02

Generated On: 12 Aug 2021 13:31:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3862086

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 14:02:02

Generated On: 12 Aug 2021 13:31:55

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3862086

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:31:55

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>



**US3862086**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 12 Aug 2021 13:31:55**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3862086

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

Form: Visit Date

Data signed: (b) (4) 03 May 2021 15:46:29

Generated On: 12 Aug 2021 13:31:55

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 \_\_\_\_\_

US3862086

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:17:16

Generated On: 12 Aug 2021 13:31:55

Date of updated informed consent (dd MMM yyyy)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3862086

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Apr 2021 16:49:09

Generated On: 12 Aug 2021 13:31:55

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3862086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 30 Apr 2021 16:49:09

Generated On: 12 Aug 2021 13:31:55

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3862086

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Mar 2021 15:14:45

Generated On: 12 Aug 2021 13:31:55

---

Did the participant experience any adverse events?

Yes ☐

No ☒

---

If Yes, enter details on the Adverse Events form.

---

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Mar 2021 14:02:02

Generated On: 12 Aug 2021 13:31:55

---

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

Yes ☒

No ☐

---

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

---

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

Name of Medication VENLAFAXINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 225

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL 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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

Name of Medication LANSOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

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

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

Name of Medication MIFEPRISTONE

Prophylaxis Yes ☐  
No ☒

Indication ELECTIVE TERMINATION OF  
PREGNANCY

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	8 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

Name of Medication MISOPROSTOL

Prophylaxis Yes ☐  
No ☒

Indication ELECTIVE TERMINATION OF PREGNANCY

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	BUCCALLY	
Start date (dd MMM yyyy)	9 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	9 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

Name of Medication ZOLPIDEM

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY AND INSOMNIA

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Mar 2021 14:02:01

Generated On: 12 Aug 2021 13:31:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3862086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Mar 2021 14:02:02

Generated On: 12 Aug 2021 13:31:55

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---



US3862086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Mar 2021 14:02:02

Generated On: 12 Aug 2021 13:31:55

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
8 OCT 2020	ELECTIVE MEDICAL TERMINATION OF INTRAUTERINE PREGNANCY	Other	PREGNANCY

US3862086

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 02 Apr 2021 14:17:16

Generated On: 12 Aug 2021 13:31:55

Date of dosing discontinuation (dd MMM yyyy) 25 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input checked="" type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

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

US3862086

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 29 Mar 2021 14:02:02

Generated On: 12 Aug 2021 13:31:55

Date of study discontinuation/completion (dd MMM yyyy) 14 JAN 2021

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify SUBJECT UBLINDED FOR EUA VACCINE

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

Audit

US3862086 (Prod: Baylor College of Medicine)

**US3862086**

**Form: Participant Creation**

**Generated On: 12 Aug 2021 13:31:55**

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:40:35
User entered 'US3862086'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 20:04:31

US3862086

Form: Participant Creation

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:31:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:56
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:01:40

US3862086

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 17:44:56
User entered '28 AUG 2020'	RWS_ENDPOINT	28 Aug 2020 20:04:32
	ENDPOINT (b) (4)	
	(b) (4)	



US3862086

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:56
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:01:40

**US3862086**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'SCRN'	System	28 Aug 2020 22:01:40

US3862086

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:34
User entered (b) (6) 1992'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 20:04:33

US3862086

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:55

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:34
User entered '28'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:01:18

**US3862086**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:31:55**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'YEARS'	System	31 Aug 2020 15:01:18

**US3862086**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:31:55**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '28'	System	28 Aug 2020 22:01:48

US3862086

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:55

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:34
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:01:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:01:29
User entered 'Female (F)' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:01:29
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:01:18
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:01:18

US3862086

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:01:18



**US3862086**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:31:55**

**White**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:34
User entered 'l'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:01:18

US3862086

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:55

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:34
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:01:18

**US3862086**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:31:55**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:34
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:01:18

US3862086

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:29:47
User closed query 'Per subject's intake form, American Indian/Alaskan Native is also marked. Please update ' (Site from CRA).		26 Oct 2020 16:29:46
Query 'Per subject's intake form, American Indian/Alaskan Native is also marked. Please update ' answered with 'completed' (Site from CRA).	Chanei Henry (b) (4) (b) (4)	02 Oct 2020 21:47:44
User entered '1' reason for change: Data Entry Error	Chanei Henry (b) (4)	02 Oct 2020 21:47:36
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:40
DataPoint Verified.		01 Oct 2020 18:27:34
User opened query 'Per subject's intake form, American Indian/Alaskan Native is also marked. Please update ' (Site from CRA).		01 Oct 2020 18:25:49
Query 'Per subject's intake form, American Indian/Alaskan Native is also marked.' canceled (Site from CRA).		01 Oct 2020 18:25:42
User opened query 'Per subject's intake form, American Indian/Alaskan Native is also marked.' (Site from CRA).		01 Oct 2020 18:25:27
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:01:18

**US3862086**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:31:55**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:34
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:01:18

**US3862086**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:31:55**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:34
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:01:18

US3862086

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:55

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:34
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:01:18

US3862086

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:55

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:34
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:01:18



US3862086

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:55

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:34
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:01:18

US3862086

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:55

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:40:10
User entered '28 Aug 2020'	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:01:48

**US3862086**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Aug 2020'	System	28 Aug 2020 22:01:48

**US3862086**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2020'	System	28 Aug 2020 22:01:48

**US3862086**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:31:55**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:40:10
User entered 'Amendment 3 (3)'	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:01:48

US3862086

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:40:10
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:01:48

US3862086

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:55

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:40:10
User entered empty.	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:01:48

US3862086

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:40:10
User entered empty.	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:01:48



US3862086

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:40:10
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:01:48

US3862086

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:40:10
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 20:04:32

**US3862086**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:31:55**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1'	System	28 Aug 2020 22:01:52

US3862086

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:40:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:01:52

US3862086

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:31:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
User closed query 'Per source, subject also reports ongoing conditions of eczema, anxiety, insomnia, drug allergy to ribavirin, and drug allergy to PCN. Please enter in EDC.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:40:44
Query 'Per source, subject also reports ongoing conditions of eczema, anxiety, insomnia, drug allergy to ribavirin, and drug allergy to PCN. Please enter in EDC.' answered with 'Date updated' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:33:42
User opened query 'Per source, subject also reports ongoing conditions of eczema, anxiety, insomnia, drug allergy to ribavirin, and drug allergy to PCN. Please enter in EDC.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 18:37:49
DataPoint Verified.		01 Oct 2020 18:30:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:49:52
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:03:58
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:03:01

US3862086

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:16
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma exercise induced, LLT: Exercise induced asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:52:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:52:35
Data point term sent to Coder	System	31 Aug 2020 16:51:31
User entered 'Exercise Induced Asthma'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:50:41

US3862086

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:16
User entered 'un UNK 2012'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:50:41

US3862086

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:16
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:50:41



US3862086

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:16
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:50:41

US3862086

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:16
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:50:41

US3862086

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:16
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:50:41

**US3862086**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Jan 2012'	System	31 Aug 2020 16:50:41

**US3862086**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2012'	System	31 Aug 2020 16:50:41

**US3862086**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 16:50:41

**US3862086**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 16:50:41

US3862086

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:21
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:53:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:53:33
Data point term sent to Coder	System	31 Aug 2020 16:52:33
User entered 'Endometriosis'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:51:49



US3862086

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:21
User entered 'UN UNK 2014'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:51:49

US3862086

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:21
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:51:49

US3862086

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:21
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:51:49

US3862086

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:21
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:51:49

US3862086

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:21
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:51:49

US3862086

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Jan 2014'	System	31 Aug 2020 16:51:49

**US3862086**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2014'	System	31 Aug 2020 16:51:49

**US3862086**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 16:51:49



**US3862086**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 16:51:49

US3862086

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:31:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:02
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:53:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:53:34
Data point term sent to Coder	System	31 Aug 2020 16:52:33
User entered 'Migraines'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:52:12

US3862086

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:31:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:29:20
User closed query 'Per source, start date was 2006. Please update year.' (Site from CRA).	(b) (4)	26 Oct 2020 16:29:19
Query 'Per source, start date was 2006. Please update year.' answered with 'Error corrected' (Site from CRA).	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:26:34
User entered 'UN UNK 2006' reason for change: Data Entry Error	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:26:17
User opened query 'Per source, start date was 2006. Please update year.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 18:33:59
User entered 'un UNK 2014'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:52:12

US3862086

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:03
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:52:12

US3862086

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:31:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:05
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:52:12

US3862086

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:07
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:52:12

US3862086

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:31:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:08
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:52:12

**US3862086**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Jan 2006'	System	10 Oct 2020 19:26:17
User entered 'Jan 2014'	System	31 Aug 2020 16:52:12



**US3862086**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2006'	System	10 Oct 2020 19:26:17
User entered '2014'	System	31 Aug 2020 16:52:12

**US3862086**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 16:52:12

**US3862086**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 16:52:12

US3862086

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:31:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:25
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:54:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:54:33
Data point term sent to Coder	System	31 Aug 2020 16:53:34
User entered 'Seasonal Allergies'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:53:16

US3862086

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:25
User entered 'un UNK 2019'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:53:16

US3862086

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:25
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:53:16

US3862086

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:31:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:53:16

US3862086

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:25
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:53:16



US3862086

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:31:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:25
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:53:16

**US3862086**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Jan 2019'	System	31 Aug 2020 16:53:16

**US3862086**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2019'	System	31 Aug 2020 16:53:16

**US3862086**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 16:53:16

**US3862086**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 16:53:16

US3862086

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:31:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:29
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) (b) (4)	31 Aug 2020 16:55:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:55:35
Data point term sent to Coder	System	31 Aug 2020 16:54:35
User entered 'Depression'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:53:37

US3862086

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:29
User entered 'un UNK 2018'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:53:37

US3862086

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:29
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:53:37



US3862086

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:31:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:29
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:53:37

US3862086

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:29
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:53:37

**US3862086**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:31:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:34:29
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:53:37

**US3862086**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Jan 2018'	System	31 Aug 2020 16:53:37

US3862086

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:31:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2018'	System	31 Aug 2020 16:53:37

**US3862086**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 16:53:37

**US3862086**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 16:53:37

US3862086

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:31:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:36:02
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:57:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:57:40
Data point term sent to Coder	System	31 Aug 2020 16:55:38
User entered 'Gastroesophageal Reflux Disease'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:54:56



US3862086

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:31:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:29:30
User closed query 'Per source, start date was APR2020. Please update month' (Site from CRA).	(b) (4)	26 Oct 2020 16:29:29
Query 'Per source, start date was APR2020. Please update month' answered with 'Error corrected' (Site from CRA).	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:27:24
User entered 'UN Apr 2020' reason for change: Data Entry Error	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:27:12
User opened query 'Per source, start date was APR2020. Please update month' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 18:34:56
User entered 'un UNK 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:54:56

US3862086

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:36:04
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:54:56

US3862086

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:31:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:36:06
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:54:56

US3862086

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:36:07
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:54:56

US3862086

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:31:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:36:09
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:54:56

**US3862086**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Apr 2020'	System	10 Oct 2020 19:27:12
User entered 'Jan 2020'	System	31 Aug 2020 16:54:56

**US3862086**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2020'	System	31 Aug 2020 16:54:56

**US3862086**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 16:54:56



**US3862086**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 16:54:56

US3862086

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:31:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:53:41
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:04:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:04:21
Data point term sent to Coder	System	06 Nov 2020 20:03:11
User entered 'Eczema'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:13

US3862086

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:53:45
User entered 'un UNK 1995'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:13

US3862086

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:53:47
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:13

US3862086

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:31:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:53:49
User entered 'Yes (Y)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:13

US3862086

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:53:51
User entered empty.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:13

US3862086

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:31:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:53:53
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:13

**US3862086**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Jan 1995'	System	06 Nov 2020 20:02:13



**US3862086**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1995'	System	06 Nov 2020 20:02:13

**US3862086**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 20:02:13

**US3862086**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 20:02:13

US3862086

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:31:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:02
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) (b) (4)	06 Nov 2020 20:04:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:04:20
Data point term sent to Coder	System	06 Nov 2020 20:03:11
User entered 'anxiety'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:37

US3862086

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:04
User entered 'UN UNK 2019' reason for change:	Shetel Anassi (b) (4)	06 Nov 2020 20:03:14
Data Entry Error	(b) (4)	
User entered 'un UNK 1995'	Shetel Anassi (b) (4)	06 Nov 2020 20:02:37
	(b) (4)	

**US3862086**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:31:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:06
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:37

US3862086

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:31:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:09
User entered 'Yes (Y)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:37

**US3862086**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:11
User entered empty.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:37



US3862086

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:31:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:13
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:37

**US3862086**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Jan 2019'	System	06 Nov 2020 20:03:14
User entered 'Jan 1995'	System	06 Nov 2020 20:02:37

**US3862086**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2019'	System	06 Nov 2020 20:03:14
User entered '1995'	System	06 Nov 2020 20:02:37

**US3862086**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 20:02:37

**US3862086**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 20:02:37

US3862086

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:31:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:17
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:04:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:04:22
Data point term sent to Coder	System	06 Nov 2020 20:03:12
User entered 'insomnia'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:55

US3862086

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:18
User entered 'un UNK 2019'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:55

**US3862086**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:31:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:20
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:55



**US3862086**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:31:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:22
User entered 'Yes (Y)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:55

**US3862086**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:24
User entered empty.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:55

US3862086

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:31:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:26
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:02:55

**US3862086**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Jan 2019'	System	06 Nov 2020 20:02:55

**US3862086**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2019'	System	06 Nov 2020 20:02:55

**US3862086**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 20:02:55

**US3862086**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 20:02:55

US3862086

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:31:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:39
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Uterine dilation and curettage, LLT: Endometrial curettage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 11:24:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 11:24:30
Data point term sent to Coder	System	06 Nov 2020 20:05:13
User entered 'endometrial excision'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:04:48



US3862086

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:41
User entered 'un Jul 2017'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:04:48

US3862086

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:43
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:04:48

US3862086

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:31:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:44
User entered 'No (N)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:04:48

US3862086

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:46
User entered 'un Jul 2017'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:04:48

US3862086

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:31:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:54:48
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:04:48

**US3862086**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Jul 2017'	System	06 Nov 2020 20:04:48

**US3862086**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2017'	System	06 Nov 2020 20:04:48

US3862086

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Jul 2017'	System	06 Nov 2020 20:04:48



**US3862086**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2017'	System	06 Nov 2020 20:04:48

US3862086

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:31:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
User closed query 'Source does not indicate that this condition is NCS. If NCS, please confirm and remove from EDC.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:51:41
Query 'Source does not indicate that this condition is NCS. If NCS, please confirm and remove from EDC.' answered with 'CS TO MH. INFORMATION CORRECT.' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	23 Nov 2020 16:29:23
User opened query 'Source does not indicate that this condition is NCS. If NCS, please confirm and remove from EDC.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 16:15:49
User closed query 'All surgeries require a corresponding condition that caused the surgery. Please document or confirm if this was NCS and not needed on medical history.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 16:15:49
Query 'All surgeries require a corresponding condition that caused the surgery. Please document or confirm if this was NCS and not needed on medical history.' answered with 'ncs' (Site from CRA).	Trent Davis (b) (4) (b) (4)	13 Nov 2020 23:00:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:55:44
User opened query 'All surgeries require a corresponding condition that caused the surgery. Please document or confirm if this was NCS and not needed on medical history.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 17:55:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:07:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:07:25
Data point term sent to Coder	System	06 Nov 2020 20:06:14
User entered 'tonsillectomy'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:05:39

US3862086

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:55:46
User entered 'un Aug 2015'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:05:39

US3862086

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:55:48
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:05:39

US3862086

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:31:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:55:49
User entered 'No (N)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:05:39

**US3862086**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:55:54
User entered 'un Aug 2015'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:05:39

US3862086

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:31:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:55:57
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:05:39

**US3862086**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Aug 2015'	System	06 Nov 2020 20:05:39



**US3862086**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2015'	System	06 Nov 2020 20:05:39

**US3862086**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Aug 2015'	System	06 Nov 2020 20:05:39

**US3862086**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2015'	System	06 Nov 2020 20:05:39

US3862086

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:31:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
User closed query 'All surgeries require a corresponding condition that caused the surgery. Please document or confirm if this was NCS and not needed on medical history.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:16:05
Query 'All surgeries require a corresponding condition that caused the surgery. Please document or confirm if this was NCS and not needed on medical history.' answered with 'ncs' (Site from CRA).	Trent Davis (b) (4) (b) (4)	13 Nov 2020 23:00:22
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:56:20
User opened query 'All surgeries require a corresponding condition that caused the surgery. Please document or confirm if this was NCS and not needed on medical history.' (Site from CRA).		11 Nov 2020 17:56:17
User coded data point as SOC: Investigations, HLT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy L knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:08:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:08:22
Data point term sent to Coder	System	06 Nov 2020 20:07:15
User entered 'left knee arthroscopy'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:06:30

**US3862086**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:56:23
User entered 'un Feb 2008'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:06:30

US3862086

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:56:24
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:06:30

**US3862086**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:31:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:56:26
User entered 'No (N)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:06:30

US3862086

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:56:29
User entered 'un Feb 2008'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:06:30



US3862086

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:31:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:56:30
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:06:30

US3862086

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Feb 2008'	System	06 Nov 2020 20:06:30

**US3862086**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2008'	System	06 Nov 2020 20:06:30

**US3862086**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Feb 2008'	System	06 Nov 2020 20:06:30

**US3862086**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2008'	System	06 Nov 2020 20:06:30

US3862086

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:31:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:11
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: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:27:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:27:22
Data point term sent to Coder	System	06 Nov 2020 20:07:15
User entered 'allergy to ribavirin'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:07:02

US3862086

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:13
User entered '20 Mar 2019'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:07:02

US3862086

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:14
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:07:02



**US3862086**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:31:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:16
User entered 'Yes (Y)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:07:02

US3862086

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:18
User entered empty.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:07:02

US3862086

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:31:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:20
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:07:02

**US3862086**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Mar 2019'	System	06 Nov 2020 20:07:02

**US3862086**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2019'	System	06 Nov 2020 20:07:02

**US3862086**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 20:07:02

**US3862086**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 20:07:02

US3862086

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:31:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:01:07
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: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:09:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:09:20
Data point term sent to Coder	System	06 Nov 2020 20:08:16
User entered 'allergy to PCN'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:07:24



US3862086

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:01:10
User entered 'un UNK 2008'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:07:24

US3862086

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:01:12
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:07:24

US3862086

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:31:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:01:14
User entered 'Yes (Y)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:07:24

US3862086

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:01:15
User entered empty.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:07:24

US3862086

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:31:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:01:17
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:07:24

**US3862086**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Jan 2008'	System	06 Nov 2020 20:07:24

**US3862086**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2008'	System	06 Nov 2020 20:07:24

**US3862086**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 20:07:24



**US3862086**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 20:07:24

US3862086

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:31:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.	(b) (4)	02 Apr 2021 17:21:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Exposures, chemical injuries and poisoning, HLT: Exposures to agents or circumstances NEC, PT: Exposure to communicable disease, LLT: Hepatitis C exposure - version MedDRA\\23.0.	Coder Import (b) (4)	12 Dec 2020 20:36:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Dec 2020 20:36:00
Data point term sent to Coder	System	10 Dec 2020 22:03:21
User entered 'EXPOSURE TO HEPATITIS C'	Trent Davis (b) (4)	10 Dec 2020 22:03:00
	(b) (4)	

US3862086

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:21:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
User entered '20 Mar 2019'	(b) (4)	
	Trent Davis (b) (4)	10 Dec 2020 22:03:00
	(b) (4)	

**US3862086**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:31:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:21:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	10 Dec 2020 22:03:00

**US3862086**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:31:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:21:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
User entered 'No (N)'	(b) (4) Trent Davis (b) (4) (b) (4)	10 Dec 2020 22:03:00

**US3862086**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:21:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
User entered '20 Mar 2019'	(b) (4)	
	Trent Davis (b) (4)	10 Dec 2020 22:03:00
	(b) (4)	

**US3862086**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:31:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:21:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	10 Dec 2020 22:03:00

**US3862086**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Mar 2019'	System	10 Dec 2020 22:03:00



**US3862086**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2019'	System	10 Dec 2020 22:03:00

**US3862086**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'Mar 2019'	System	10 Dec 2020 22:03:00

**US3862086**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '2019'	System	10 Dec 2020 22:03:00

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:20
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:53:59

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:20
User entered '28 Aug 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:53:59

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:20
User entered '14:08'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:53:59

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '28 Aug 2020 14:08'	System	31 Aug 2020 15:53:59

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:20
User entered '065.5' in	Trent Davis (b) (4)	31 Aug 2020 15:53:59
DataPoint set to visible.	(b) (4) System	28 Aug 2020 22:01:52



US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:20
User entered '225.5' lb	Trent Davis (b) (4)	31 Aug 2020 15:53:59
DataPoint set to visible.	(b) (4) System	28 Aug 2020 22:01:52

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '37.03172'	System	31 Aug 2020 15:53:59
DataPoint set to visible.	System	28 Aug 2020 22:01:52

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'kg/m2'	System	31 Aug 2020 15:53:59
DataPoint set to visible.	System	28 Aug 2020 22:01:52

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:51:48
DataPoint Un-verified.	Trent Davis (b) (4) (b) (4)	20 Oct 2020 16:56:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	20 Oct 2020 16:56:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:42:20
User entered '98.9' F	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:53:59

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:51:49
User closed query 'Per source, route was oral. Please update.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 16:30:04
Query 'Per source, route was oral. Please update.' answered with 'data corrected' (Site from CRA).	Trent Davis (b) (4)	20 Oct 2020 16:56:50
DataPoint Un-verified.	(b) (4)	
	Trent Davis (b) (4)	20 Oct 2020 16:56:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Trent Davis (b) (4)	20 Oct 2020 16:56:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:42:20
User opened query 'Per source, route was oral. Please update.' (Site from CRA).		01 Oct 2020 18:41:50
User entered 'Other (Other)' reason for change: Data Entry Error	Trent Davis (b) (4)	31 Aug 2020 16:42:38
	(b) (4)	
User entered 'Oral (Oral)'	Trent Davis (b) (4)	31 Aug 2020 15:53:59
	(b) (4)	

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:51:45
DataPoint Un-verified.	Trent Davis (b) (4) (b) (4)	20 Oct 2020 16:56:39
User entered empty; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	20 Oct 2020 16:56:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:42:20
User entered 'temporal' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:42:38
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:53:59

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:51:41
DataPoint Un-verified.	Trent Davis (b) (4)	20 Oct 2020 16:56:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Trent Davis (b) (4)	20 Oct 2020 16:56:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:20
User entered '80'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:53:59

**US3862086**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'bpm'	System	31 Aug 2020 15:53:59



US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:51:39
DataPoint Un-verified.	Trent Davis (b) (4)	20 Oct 2020 16:56:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Trent Davis (b) (4)	20 Oct 2020 16:56:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:20
User entered '14'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:53:59

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'breaths/min'	System	31 Aug 2020 15:53:59

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:51:44
DataPoint Un-verified.	Trent Davis (b) (4)	20 Oct 2020 16:56:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Trent Davis (b) (4)	20 Oct 2020 16:56:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:42:20
User entered '128'	Trent Davis (b) (4)	31 Aug 2020 15:53:59
	(b) (4)	

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'mmHg'	System	31 Aug 2020 15:53:59

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:51:38
DataPoint Un-verified.	Trent Davis (b) (4)	20 Oct 2020 16:56:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Trent Davis (b) (4)	20 Oct 2020 16:56:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:20
User entered '082'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:53:59

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'mmHg'	System	31 Aug 2020 15:53:59

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56



US3862086

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:45
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:02:01

US3862086

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:45
User entered '28 Aug 2020'	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:02:01

US3862086

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:27:07
User entered '28 Aug 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:41:25

US3862086

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:27:09
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	31 Aug 2020 15:41:47
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	31 Aug 2020 15:41:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:41:25

US3862086

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:27:16
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:41:25

US3862086

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:55

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:27:13
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:41:25

US3862086

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:27:14
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:41:25

US3862086

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:55

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:27:18
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:41:25



US3862086

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:27:20
User entered empty; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:41:47
User entered '17 Aug 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:41:25

US3862086

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:55

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:28:45
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:41:25

**US3862086**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:55**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:43:18
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:45:07

US3862086

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:43:18
User entered '28 Aug 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:45:07

US3862086

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:43:18
User entered 'Urine (URINE)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:45:07

US3862086

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:43:18
User entered 'Negative (NEGATIVE)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:45:07

US3862086

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
User closed query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:45:24
Query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:10:16
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:43:18
User opened query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).		01 Oct 2020 12:48:23
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:45:07

US3862086

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:32
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 18:10:13
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:43:27
DataPoint Verified.		01 Oct 2020 18:43:18
User entered '28 Aug 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:45:07



US3862086

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:34
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 18:10:13
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:43:29
DataPoint Verified.		01 Oct 2020 18:43:18
User entered '15:20'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:45:07

**US3862086**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	20 Oct 2020 18:10:13
User entered '28 Aug 2020 15:20'	System	31 Aug 2020 15:45:07

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29



US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
User entered '0'	(b) (4) Trent Davis (b) (4)	31 Aug 2020 15:47:29



US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered 'I'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

US3862086

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:30:06
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:47:29

**US3862086**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:51
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:33:15



**US3862086**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:51
User entered '28 Aug 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:33:15

US3862086

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:44:51
User entered 'Clinic (Clinic)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:33:15

**US3862086**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'VISIT1'	System	31 Aug 2020 15:33:15

US3862086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:20
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 21:24:24

US3862086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:55

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:20
User entered '109877'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 21:24:24

US3862086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:20
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 21:24:24

US3862086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:20
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 19:24:38
Query 'PER CDM: Please complete this section of the form.' answered with 'data entered' (Site from DM).	Trent Davis (b) (4) (b) (4)	02 Sep 2020 18:24:12
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	02 Sep 2020 18:24:01
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 10:56:21

US3862086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:20
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	02 Sep 2020 18:24:01



US3862086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:20
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	02 Sep 2020 18:24:01

**US3862086**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:31:55**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:20
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	02 Sep 2020 18:24:01

**US3862086**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:31:55**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:20
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	02 Sep 2020 18:24:01

US3862086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:20
User entered 'No (N)'	Carrie Kibler (b) (4)	22 Sep 2020 18:00:29
Amendment Manager: DataPoint set to visible.	(b) (4)	
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:33:27
	System	19 Sep 2020 08:33:26

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:53:42
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).		22 Oct 2020 15:04:54
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:22:56
DataPoint Un-verified.	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:22:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:22:45
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:24:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered '065.5' in	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:53:44
DataPoint Un-verified.	Shetel Anassi (b) (4)	20 Oct 2020 16:22:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shetel Anassi (b) (4)	20 Oct 2020 16:22:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered '225.5' lb	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:53:42
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM). Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:22:56
DataPoint Un-verified.	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:22:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:22:45
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:24:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered '065.5' in	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:53:44
DataPoint Un-verified.	Shetel Anassi (b) (4)	20 Oct 2020 16:22:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shetel Anassi (b) (4)	20 Oct 2020 16:22:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered '225.5' lb	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User accepted default value 'Pre-Dose (PREDOSE)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered '28 Aug 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered '14:08'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '28 Aug 2020 14:08'	System	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered '98.9' F	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:30:23
User closed query 'Per source, route was oral. Please update.' (Site from CRA).		26 Oct 2020 16:30:19
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	20 Oct 2020 16:25:42
Query 'Per source, route was oral. Please update.' answered with 'Data Corrected' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:25:26
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	20 Oct 2020 16:25:09
User entered 'Oral (Oral)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:25:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:50:55
User opened query 'Per source, route was oral. Please update.' (Site from CRA).		01 Oct 2020 18:50:50
DataPoint Verified.		01 Oct 2020 18:50:29
User entered 'Other (Other)' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:43:08
User entered 'Oral (Oral)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:30:22
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 16:25:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:57
DataPoint Verified.		01 Oct 2020 18:50:29
User entered 'temporal' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:43:08
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37



US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:39:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 15:39:23
User entered '080' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:39:23
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:37:37
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'bpm'	System	31 Aug 2020 15:39:23
User entered empty.	System	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:39:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 15:39:23
User entered '14' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:39:23
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:37:37
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'breaths/min'	System	31 Aug 2020 15:39:23
User entered empty.	System	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:39:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 15:39:23
User entered '128' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:39:23
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:37:37
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'mmHg'	System	31 Aug 2020 15:39:23
User entered empty.	System	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:39:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 15:39:23
User entered '082' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:39:23
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:37:37
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'mmHg'	System	31 Aug 2020 15:39:23
User entered empty.	System	31 Aug 2020 15:37:37



US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:53:42
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM). Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:22:56
DataPoint Un-verified.	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:22:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:22:45
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:24:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered '065.5' in	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:53:44
DataPoint Un-verified.	Shetel Anassi (b) (4)	20 Oct 2020 16:22:45
User entered missing code ND - Not Done; reason for	(b) (4)	20 Oct 2020 16:22:45
change Data Entry Error	Shetel Anassi (b) (4)	
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered '225.5' lb	Trent Davis (b) (4)	31 Aug 2020 15:37:37
	(b) (4)	

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User accepted default value 'Post-Dose (POSTDOSE)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered '28 Aug 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered '17:14'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '28 Aug 2020 17:14'	System	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered '98.3' F	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37



US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered 'Other (Other)' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 16:43:08
User entered 'Oral (Oral)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User entered 'temporal' reason for change: Data Entry Error	Trent Davis (b) (4)	31 Aug 2020 16:43:08
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:39:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 15:39:23
User entered '083' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:39:23
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:37:37
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'bpm'	System	31 Aug 2020 15:39:23
User entered empty.	System	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:39:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 15:39:23
User entered '021' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:39:23
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:37:37
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'breaths/min'	System	31 Aug 2020 15:39:23
User entered empty.	System	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:39:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 15:39:23
User entered '125' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:39:23
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:37:37
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'mmHg'	System	31 Aug 2020 15:39:23
User entered empty.	System	31 Aug 2020 15:37:37



US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:50:29
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:39:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 15:39:23
User entered '083' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:39:23
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:37:37
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'mmHg'	System	31 Aug 2020 15:39:23
User entered empty.	System	31 Aug 2020 15:37:37

US3862086

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:29
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:34:31

US3862086

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:29
User entered '28 Aug 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:34:31

US3862086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:30:33
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 VID1 to avoid duplication. Please review and update accordingly.' (Site from DM).		22 Oct 2020 15:05:07
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 VID1 to avoid duplication. Please review and update accordingly.' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:10:55
DataPoint Un-verified.	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:10:45
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:10:45
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 VID1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:27:35
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:45:37
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:51:21

US3862086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:30:35
DataPoint Un-verified.	Shetel Anassi (b) (4)	20 Oct 2020 18:10:45
User entered empty; reason for change Data Entry Error	(b) (4) Shetel Anassi (b) (4)	20 Oct 2020 18:10:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:37
User entered '28 Aug 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:51:21

US3862086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:30:35
DataPoint Un-verified.	Shetel Anassi (b) (4)	20 Oct 2020 18:10:45
User entered empty; reason for change Data Entry Error	(b) (4) Shetel Anassi (b) (4)	20 Oct 2020 18:10:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:37
User entered 'Urine (URINE)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:51:21

US3862086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:30:35
DataPoint Un-verified.	Shetel Anassi (b) (4)	20 Oct 2020 18:10:45
User entered empty; reason for change Data Entry Error	(b) (4) Shetel Anassi (b) (4)	20 Oct 2020 18:10:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:37
User entered 'Negative (NEGATIVE)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:51:21



US3862086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:30:35
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 18:10:50
DataPoint Un-verified.	(b) (4) Shetel Anassi (b) (4)	20 Oct 2020 18:10:45
User entered empty; reason for change Data Entry Error	(b) (4) Shetel Anassi (b) (4)	20 Oct 2020 18:10:45
Query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' canceled (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:27:38
DataPoint Verified.		01 Oct 2020 18:45:37
User opened query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).		01 Oct 2020 12:48:33
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:51:21

US3862086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:30:35
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 18:10:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:40
DataPoint Verified.		01 Oct 2020 18:45:37
User entered '28 Aug 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:51:21

US3862086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:30:35
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 18:10:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:41
DataPoint Verified.		01 Oct 2020 18:45:37
User entered '15:20'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:51:21

**US3862086**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	20 Oct 2020 18:10:45
User entered '28 Aug 2020 15:20'	System	31 Aug 2020 15:51:21

US3862086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:47:26
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:02:48

US3862086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:47:26
User entered empty.	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:02:48

US3862086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:47:26
User entered empty.	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:02:48

US3862086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 22:02:48



US3862086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:47:26
User entered '28 Aug 2020'	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:02:48

US3862086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:47:26
User entered '16:44'	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:02:48

US3862086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '28 Aug 2020 16:44'	System	28 Aug 2020 22:02:48

US3862086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:47:26
User entered 'Left Arm (LEFT ARM)'	Carrie Kibler (b) (4) (b) (4)	28 Aug 2020 22:02:48

US3862086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		01 Oct 2020 18:47:26
User entered 'ONCE'	System	28 Aug 2020 22:02:48

US3862086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 22:02:48

US3862086

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:51
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:49:40

US3862086

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:51
User entered '28 Aug 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:49:40



US3862086

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:51
User entered '15:50'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:49:40

**US3862086**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '28 Aug 2020 15:50'	System	31 Aug 2020 15:49:40

US3862086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:31:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:00
User entered '28 Aug 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:50:10

US3862086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:50:10

US3862086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:00
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:50:10

US3862086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:00
User entered '15:15'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:50:10

**US3862086**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '28 Aug 2020 15:15'	System	31 Aug 2020 15:50:10

US3862086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:50:10



US3862086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:00
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:50:10

US3862086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:00
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:50:10

**US3862086**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 15:50:10

US3862086

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:31:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:46:22
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 15:39:40

**US3862086**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1'	System	31 Aug 2020 15:39:40

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User closed query 'Per source, post-dose temperature was 98.3. Please confirm which temperature is correct.' (Site from CRA).		29 Oct 2020 14:58:04
Query 'Per source, post-dose temperature was 98.3. Please confirm which temperature is correct.' answered with '98.3 is correct temperature' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	27 Oct 2020 19:55:22
User opened query 'Per source, post-dose temperature was 98.3. Please confirm which temperature is correct.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 18:54:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:15:19', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '7cf0d90a-99c3-4926-a833-b0d700f39db2'	System	28 Aug 2020 22:15:58
User entered 'Yes (Y)'	System	28 Aug 2020 22:15:58

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:15:24', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '7cf0d90a-99c3-4926-a833-b0d700f39db2' User entered '98.0'	System	28 Aug 2020 22:15:58
	System	28 Aug 2020 22:15:58



US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:15:33', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '7cf0d90a-99c3-4926-a833-b0d700f39db2'	System	28 Aug 2020 22:15:58
User entered 'No (N)'	System	28 Aug 2020 22:15:58

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:15:56', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '7cf0d90a-99c3-4926-a833-b0d700f39db2'	System	28 Aug 2020 22:15:58
User entered '28 Aug 2020 17:15'	System	28 Aug 2020 22:15:58

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '28 Aug 2020 17:04'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '28 Aug 2020 19:34'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:08:04', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '0522cbe5-bc95-4d9c-b1a5-afd5c4973b42'	System	29 Aug 2020 03:14:50
User entered 'Yes (Y)'	System	29 Aug 2020 03:14:50

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:14:40', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '0522cbe5-bc95-4d9c-b1a5-afd5c4973b42' User entered '99.1'	System	29 Aug 2020 03:14:50
	System	29 Aug 2020 03:14:50

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:14:43', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '0522cbe5-bc95-4d9c-b1a5-afd5c4973b42'	System	29 Aug 2020 03:14:50
User entered 'No (N)'	System	29 Aug 2020 03:14:50



US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:14:46', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '0522cbe5-bc95-4d9c-b1a5-afd5c4973b42'	System	29 Aug 2020 03:14:50
User entered '28 Aug 2020 22:14'	System	29 Aug 2020 03:14:50

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '28 Aug 2020 20:29'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 2'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:12:38', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '9e16e3b5-c852-4830-a816-59664fdabc7e'	System	29 Aug 2020 19:14:35
User entered 'Yes (Y)'	System	29 Aug 2020 19:14:35

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:14:25', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '9e16e3b5-c852-4830-a816-59664fdabc7e' User entered '97.5'	System	29 Aug 2020 19:14:35
	System	29 Aug 2020 19:14:35

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:14:28', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '9e16e3b5-c852-4830-a816-59664fdabc7e'	System	29 Aug 2020 19:14:35
User entered 'No (N)'	System	29 Aug 2020 19:14:35

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:14:30', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '9e16e3b5-c852-4830-a816-59664fdabc7e'	System	29 Aug 2020 19:14:35
User entered '29 Aug 2020 14:14'	System	29 Aug 2020 19:14:35



US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 3'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:49:45', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8098a208-c97c-4fca-aa90-59213bc1f9e7'	System	31 Aug 2020 02:49:55
User entered 'Yes (Y)'	System	31 Aug 2020 02:49:55

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:49:49', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8098a208-c97c-4fca-aa90-59213bc1f9e7' User entered '97.2'	System	31 Aug 2020 02:49:55
	System	31 Aug 2020 02:49:55

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:49:51', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8098a208-c97c-4fca-aa90-59213bc1f9e7'	System	31 Aug 2020 02:49:55
User entered 'No (N)'	System	31 Aug 2020 02:49:55

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:49:53', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8098a208-c97c-4fca-aa90-59213bc1f9e7'	System	31 Aug 2020 02:49:55
User entered '30 Aug 2020 21:49'	System	31 Aug 2020 02:49:55

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 22:02:48



US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 4'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:43:52', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'c8a79b80-839c-4f07-9457-4fb55eca6dad' User entered 'Yes (Y)'	System	31 Aug 2020 22:44:04
	System	31 Aug 2020 22:44:04

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:43:55', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'c8a79b80-839c-4f07-9457-4fb55eca6dad' User entered '97.7'	System	31 Aug 2020 22:44:04
	System	31 Aug 2020 22:44:04

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:43:58', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'c8a79b80-839c-4f07-9457-4fb55eca6dad'	System	31 Aug 2020 22:44:04
User entered 'No (N)'	System	31 Aug 2020 22:44:04

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:01', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'c8a79b80-839c-4f07-9457-4fb55eca6dad' User entered '31 Aug 2020 17:44'	System	31 Aug 2020 22:44:04
	System	31 Aug 2020 22:44:04

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 22:02:48



US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 5'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:07', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '479220d2-d98c-4da4-bb2a-aa7c5d7b4396' User entered 'Yes (Y)'	System	02 Sep 2020 03:22:19
	System	02 Sep 2020 03:22:19

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:10', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '479220d2-d98c-4da4-bb2a-aa7c5d7b4396' User entered '97.2'	System	02 Sep 2020 03:22:19
	System	02 Sep 2020 03:22:19

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:12', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '479220d2-d98c-4da4-bb2a-aa7c5d7b4396'	System	02 Sep 2020 03:22:19
User entered 'No (N)'	System	02 Sep 2020 03:22:19

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:15', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '479220d2-d98c-4da4-bb2a-aa7c5d7b4396' User entered '01 Sep 2020 22:22'	System	02 Sep 2020 03:22:19
	System	02 Sep 2020 03:22:19

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 6'	System	28 Aug 2020 22:02:48



US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:10:31', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'fc9cb818-304a-4f02-88c1-3fc54eabeef6'	System	03 Sep 2020 03:10:42
User entered 'Yes (Y)'	System	03 Sep 2020 03:10:42

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:10:34', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'fc9cb818-304a-4f02-88c1-3fc54eabeef6' User entered '97.9'	System	03 Sep 2020 03:10:42
	System	03 Sep 2020 03:10:42

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:10:37', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'fc9cb818-304a-4f02-88c1-3fc54eabeef6'	System	03 Sep 2020 03:10:42
User entered 'No (N)'	System	03 Sep 2020 03:10:42

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:10:40', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'fc9cb818-304a-4f02-88c1-3fc54eabeef6'	System	03 Sep 2020 03:10:42
User entered '02 Sep 2020 22:10'	System	03 Sep 2020 03:10:42

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 7'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:13', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'afba8454-9f01-497f-8ee4-53d711fb86c8' User entered 'Yes (Y)'	System	04 Sep 2020 02:23:24
	System	04 Sep 2020 02:23:24



US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:16', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'afba8454-9f01-497f-8ee4-53d711fb86c8' User entered '96.8'	System	04 Sep 2020 02:23:24
	System	04 Sep 2020 02:23:24

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:19', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'afba8454-9f01-497f-8ee4-53d711fb86c8'	System	04 Sep 2020 02:23:24
User entered 'No (N)'	System	04 Sep 2020 02:23:24

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:22', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'afba8454-9f01-497f-8ee4-53d711fb86c8'	System	04 Sep 2020 02:23:24
User entered '03 Sep 2020 21:23'	System	04 Sep 2020 02:23:24

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:16:45', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '804f0767-8afc-4c50-9377-b4a7086794b1' User entered 'None (1)'	System	28 Aug 2020 22:17:06
	System	28 Aug 2020 22:17:06

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:16:47', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '804f0767-8afc-4c50-9377-b4a7086794b1'	System	28 Aug 2020 22:17:06
User entered 'No (N)'	System	28 Aug 2020 22:17:06



US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:16:57', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '804f0767-8afc-4c50-9377-b4a7086794b1'	System	28 Aug 2020 22:17:06
User entered 'No (N)'	System	28 Aug 2020 22:17:06

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:17:00', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '804f0767-8afc-4c50-9377-b4a7086794b1' User entered 'None (1)'	System	28 Aug 2020 22:17:06
	System	28 Aug 2020 22:17:06

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:17:02', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '804f0767-8afc-4c50-9377-b4a7086794b1' User entered '28 Aug 2020 17:17'	System	28 Aug 2020 22:17:06
	System	28 Aug 2020 22:17:06

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '28 Aug 2020 17:04'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '28 Aug 2020 19:34'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:14:54', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'a9cee760-5079-4159-887e-22aa4c58c519' User entered 'None (1)'	System	29 Aug 2020 03:15:38
	System	29 Aug 2020 03:15:38

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:14:58', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'a9cee760-5079-4159-887e-22aa4c58c519'	System	29 Aug 2020 03:15:38
User entered 'No (N)'	System	29 Aug 2020 03:15:38



US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:15:06', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'a9cee760-5079-4159-887e-22aa4c58c519'	System	29 Aug 2020 03:15:38
User entered 'No (N)'	System	29 Aug 2020 03:15:38

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:15:31', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'a9cee760-5079-4159-887e-22aa4c58c519' User entered 'None (1)'	System	29 Aug 2020 03:15:38
	System	29 Aug 2020 03:15:38

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:15:33', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'a9cee760-5079-4159-887e-22aa4c58c519' User entered '28 Aug 2020 22:15'	System	29 Aug 2020 03:15:38
	System	29 Aug 2020 03:15:38

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '28 Aug 2020 20:29'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 2'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:14:39', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '932fc85a-7420-4fe9-b978-a27730a46b2d' User entered 'None (1)'	System	29 Aug 2020 19:14:59
	System	29 Aug 2020 19:14:59

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:14:43', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '932fc85a-7420-4fe9-b978-a27730a46b2d' User entered 'No (N)'	System	29 Aug 2020 19:14:59
	System	29 Aug 2020 19:14:59



US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:14:46', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '932fc85a-7420-4fe9-b978-a27730a46b2d' User entered 'No (N)'	System	29 Aug 2020 19:14:59
	System	29 Aug 2020 19:14:59

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:14:54', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '932fc85a-7420-4fe9-b978-a27730a46b2d' User entered 'None (1)'	System	29 Aug 2020 19:14:59
	System	29 Aug 2020 19:14:59

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:31:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:14:57', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '932fc85a-7420-4fe9-b978-a27730a46b2d' User entered '29 Aug 2020 14:14'	System	29 Aug 2020 19:14:59
	System	29 Aug 2020 19:14:59

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 3'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:49:59', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'a747a4ff-8612-4dd5-975c-8b975dfee6f3'	System	31 Aug 2020 02:50:10
User entered 'None (1)'	System	31 Aug 2020 02:50:10

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:50:02', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'a747a4ff-8612-4dd5-975c-8b975dfee6f3'	System	31 Aug 2020 02:50:10
User entered 'No (N)'	System	31 Aug 2020 02:50:10



US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:50:04', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'a747a4ff-8612-4dd5-975c-8b975dfee6f3'	System	31 Aug 2020 02:50:10
User entered 'No (N)'	System	31 Aug 2020 02:50:10

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:50:06', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'a747a4ff-8612-4dd5-975c-8b975dfee6f3' User entered 'None (1)'	System	31 Aug 2020 02:50:10
	System	31 Aug 2020 02:50:10

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:31:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:50:08', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'a747a4ff-8612-4dd5-975c-8b975dfee6f3'	System	31 Aug 2020 02:50:10
User entered '30 Aug 2020 21:50'	System	31 Aug 2020 02:50:10

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 4'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:05', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '0d9ec97f-14ba-49f9-8ebf-73b174d151a4'	System	31 Aug 2020 22:44:19
User entered 'None (1)'	System	31 Aug 2020 22:44:19

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:09', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '0d9ec97f-14ba-49f9-8ebf-73b174d151a4'	System	31 Aug 2020 22:44:19
User entered 'No (N)'	System	31 Aug 2020 22:44:19



US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:11', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '0d9ec97f-14ba-49f9-8ebf-73b174d151a4'	System	31 Aug 2020 22:44:19
User entered 'No (N)'	System	31 Aug 2020 22:44:19

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:13', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '0d9ec97f-14ba-49f9-8ebf-73b174d151a4'	System	31 Aug 2020 22:44:19
User entered 'None (1)'	System	31 Aug 2020 22:44:19

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:31:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:16', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '0d9ec97f-14ba-49f9-8ebf-73b174d151a4'	System	31 Aug 2020 22:44:19
User entered '31 Aug 2020 17:44'	System	31 Aug 2020 22:44:19

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 5'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:19', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'c0c49bef-3841-44f1-a1b9-c04aed090451' User entered 'None (1)'	System	02 Sep 2020 03:22:31
	System	02 Sep 2020 03:22:31

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:23', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'c0c49bef-3841-44f1-a1b9-c04aed090451' User entered 'No (N)'	System	02 Sep 2020 03:22:31
	System	02 Sep 2020 03:22:31



US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:24', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'c0c49bef-3841-44f1-a1b9-c04aed090451' User entered 'No (N)'	System	02 Sep 2020 03:22:31
	System	02 Sep 2020 03:22:31

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:26', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'c0c49bef-3841-44f1-a1b9-c04aed090451' User entered 'None (1)'	System	02 Sep 2020 03:22:31
	System	02 Sep 2020 03:22:31

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:29', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'c0c49bef-3841-44f1-a1b9-c04aed090451' User entered '01 Sep 2020 22:22'	System	02 Sep 2020 03:22:31
	System	02 Sep 2020 03:22:31

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 6'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:10:46', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b04a3295-a408-4554-96c2-06f5d7bbc45f' User entered 'None (1)'	System	03 Sep 2020 03:10:55
	System	03 Sep 2020 03:10:55

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:10:48', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b04a3295-a408-4554-96c2-06f5d7bbc45f' User entered 'No (N)'	System	03 Sep 2020 03:10:55
	System	03 Sep 2020 03:10:55



US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:10:50', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b04a3295-a408-4554-96c2-06f5d7bbc45f' User entered 'No (N)'	System	03 Sep 2020 03:10:55
	System	03 Sep 2020 03:10:55

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:10:52', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b04a3295-a408-4554-96c2-06f5d7bbc45f' User entered 'None (1)'	System	03 Sep 2020 03:10:55
	System	03 Sep 2020 03:10:55

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:31:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:10:53', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b04a3295-a408-4554-96c2-06f5d7bbc45f' User entered '02 Sep 2020 22:10'	System	03 Sep 2020 03:10:55
	System	03 Sep 2020 03:10:55

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 7'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:25', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'da55b410-3f57-4f0e-b14a-da8b6f65f6d5' User entered 'None (1)'	System	04 Sep 2020 02:23:35
	System	04 Sep 2020 02:23:35

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:28', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'da55b410-3f57-4f0e-b14a-da8b6f65f6d5' User entered 'No (N)'	System	04 Sep 2020 02:23:35
	System	04 Sep 2020 02:23:35



US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:29', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'da55b410-3f57-4f0e-b14a-da8b6f65f6d5' User entered 'No (N)'	System	04 Sep 2020 02:23:35
	System	04 Sep 2020 02:23:35

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:31', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'da55b410-3f57-4f0e-b14a-da8b6f65f6d5'	System	04 Sep 2020 02:23:35
User entered 'None (1)'	System	04 Sep 2020 02:23:35

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:33', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'da55b410-3f57-4f0e-b14a-da8b6f65f6d5' User entered '03 Sep 2020 21:23'	System	04 Sep 2020 02:23:35
	System	04 Sep 2020 02:23:35

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:16:11', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '1964eec0-f2d0-4cd8-a50a-9fb2a9194fdd'	System	28 Aug 2020 22:17:34
User entered 'None (0)'	System	28 Aug 2020 22:17:34

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:31:55**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:17:09', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '1964eec0-f2d0-4cd8-a50a-9fb2a9194fdd' User entered 'None (0)'	System	28 Aug 2020 22:17:34
	System	28 Aug 2020 22:17:34



US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:17:12', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '1964eec0-f2d0-4cd8-a50a-9fb2a9194fdd'	System	28 Aug 2020 22:17:34
User entered 'None (0)'	System	28 Aug 2020 22:17:34

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:17:14', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '1964eec0-f2d0-4cd8-a50a-9fb2a9194fdd' User entered 'None (0)'	System	28 Aug 2020 22:17:34
	System	28 Aug 2020 22:17:34

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:17:16', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '1964eec0-f2d0-4cd8-a50a-9fb2a9194fdd' User entered 'None (0)'	System	28 Aug 2020 22:17:34
	System	28 Aug 2020 22:17:34

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:17:18', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '1964eec0-f2d0-4cd8-a50a-9fb2a9194fdd'	System	28 Aug 2020 22:17:34
User entered 'None (0)'	System	28 Aug 2020 22:17:34

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:17:26', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '1964eec0-f2d0-4cd8-a50a-9fb2a9194fdd'	System	28 Aug 2020 22:17:34
User entered 'No (N)'	System	28 Aug 2020 22:17:34

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T17:17:32', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '1964eec0-f2d0-4cd8-a50a-9fb2a9194fdd' User entered '28 Aug 2020 17:17'	System	28 Aug 2020 22:17:34
	System	28 Aug 2020 22:17:34

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '28 Aug 2020 17:04'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '28 Aug 2020 19:34'	System	28 Aug 2020 22:02:48



US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 22:02:48

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:31:55**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:15:36', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '34cb6c32-f35c-475f-9325-b2da78bb3155'	System	29 Aug 2020 03:15:57
User entered 'None (0)'	System	29 Aug 2020 03:15:57

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:31:55**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:15:39', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '34cb6c32-f35c-475f-9325-b2da78bb3155'	System	29 Aug 2020 03:15:57
User entered 'None (0)'	System	29 Aug 2020 03:15:57

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:15:41', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '34cb6c32-f35c-475f-9325-b2da78bb3155'	System	29 Aug 2020 03:15:57
User entered 'None (0)'	System	29 Aug 2020 03:15:57

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:15:43', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '34cb6c32-f35c-475f-9325-b2da78bb3155'	System	29 Aug 2020 03:15:57
User entered 'None (0)'	System	29 Aug 2020 03:15:57

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:31:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:15:45', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '34cb6c32-f35c-475f-9325-b2da78bb3155'	System	29 Aug 2020 03:15:57
User entered 'None (0)'	System	29 Aug 2020 03:15:57

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:15:47', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '34cb6c32-f35c-475f-9325-b2da78bb3155'	System	29 Aug 2020 03:15:57
User entered 'None (0)'	System	29 Aug 2020 03:15:57

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:15:49', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '34cb6c32-f35c-475f-9325-b2da78bb3155'	System	29 Aug 2020 03:15:57
User entered 'No (N)'	System	29 Aug 2020 03:15:57



US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-28T22:15:52', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '34cb6c32-f35c-475f-9325-b2da78bb3155'	System	29 Aug 2020 03:15:57
User entered '28 Aug 2020 22:15'	System	29 Aug 2020 03:15:57

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '28 Aug 2020 20:29'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 2'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:15:08', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'ef354c84-0bcb-4377-a0a5-72584772c6e7' User entered 'None (0)'	System	29 Aug 2020 19:15:26
	System	29 Aug 2020 19:15:26

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:15:10', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'ef354c84-0bcb-4377-a0a5-72584772c6e7'	System	29 Aug 2020 19:15:26
User entered 'None (0)'	System	29 Aug 2020 19:15:26

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:15:12', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'ef354c84-0bcb-4377-a0a5-72584772c6e7' User entered 'None (0)'	System	29 Aug 2020 19:15:26
	System	29 Aug 2020 19:15:26

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:15:14', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'ef354c84-0bcb-4377-a0a5-72584772c6e7' User entered 'None (0)'	System	29 Aug 2020 19:15:26
	System	29 Aug 2020 19:15:26



US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:15:15', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'ef354c84-0bcb-4377-a0a5-72584772c6e7' User entered 'None (0)'	System	29 Aug 2020 19:15:26
	System	29 Aug 2020 19:15:26

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:31:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:15:17', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'ef354c84-0bcb-4377-a0a5-72584772c6e7' User entered 'None (0)'	System	29 Aug 2020 19:15:26
	System	29 Aug 2020 19:15:26

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:15:20', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'ef354c84-0bcb-4377-a0a5-72584772c6e7'	System	29 Aug 2020 19:15:26
User entered 'No (N)'	System	29 Aug 2020 19:15:26

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:31:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-29T14:15:23', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'ef354c84-0bcb-4377-a0a5-72584772c6e7'	System	29 Aug 2020 19:15:26
User entered '29 Aug 2020 14:15'	System	29 Aug 2020 19:15:26

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 3'	System	28 Aug 2020 22:02:48

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:31:55**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:50:12', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '2b8ca669-9a73-4645-93fc-963db2f6a9be' User entered 'None (0)'	System	31 Aug 2020 02:50:30
	System	31 Aug 2020 02:50:30



US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:50:13', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '2b8ca669-9a73-4645-93fc-963db2f6a9be' User entered 'None (0)'	System	31 Aug 2020 02:50:30
	System	31 Aug 2020 02:50:30

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:50:15', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '2b8ca669-9a73-4645-93fc-963db2f6a9be' User entered 'None (0)'	System	31 Aug 2020 02:50:30
	System	31 Aug 2020 02:50:30

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:50:16', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '2b8ca669-9a73-4645-93fc-963db2f6a9be' User entered 'None (0)'	System	31 Aug 2020 02:50:30
	System	31 Aug 2020 02:50:30

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:50:18', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '2b8ca669-9a73-4645-93fc-963db2f6a9be' User entered 'None (0)'	System	31 Aug 2020 02:50:30
	System	31 Aug 2020 02:50:30

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:50:22', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '2b8ca669-9a73-4645-93fc-963db2f6a9be' User entered 'None (0)'	System	31 Aug 2020 02:50:30
	System	31 Aug 2020 02:50:30

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:50:24', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '2b8ca669-9a73-4645-93fc-963db2f6a9be' User entered 'No (N)'	System	31 Aug 2020 02:50:30
	System	31 Aug 2020 02:50:30

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:31:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-30T21:50:29', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '2b8ca669-9a73-4645-93fc-963db2f6a9be' User entered '30 Aug 2020 21:50'	System	31 Aug 2020 02:50:30
	System	31 Aug 2020 02:50:30

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 22:02:48



US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 4'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:21', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '5769ac60-5e30-488a-a029-23f16f3b46a5' User entered 'None (0)'	System	31 Aug 2020 22:44:38
	System	31 Aug 2020 22:44:38

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:31:55**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:23', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '5769ac60-5e30-488a-a029-23f16f3b46a5' User entered 'None (0)'	System	31 Aug 2020 22:44:38
	System	31 Aug 2020 22:44:38

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:24', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '5769ac60-5e30-488a-a029-23f16f3b46a5' User entered 'None (0)'	System	31 Aug 2020 22:44:38
	System	31 Aug 2020 22:44:38

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:26', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '5769ac60-5e30-488a-a029-23f16f3b46a5' User entered 'None (0)'	System	31 Aug 2020 22:44:38
	System	31 Aug 2020 22:44:38

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:31:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:27', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '5769ac60-5e30-488a-a029-23f16f3b46a5' User entered 'None (0)'	System	31 Aug 2020 22:44:38
	System	31 Aug 2020 22:44:38

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:31:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:29', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '5769ac60-5e30-488a-a029-23f16f3b46a5' User entered 'None (0)'	System	31 Aug 2020 22:44:38
	System	31 Aug 2020 22:44:38



US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:32', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '5769ac60-5e30-488a-a029-23f16f3b46a5' User entered 'No (N)'	System	31 Aug 2020 22:44:38
	System	31 Aug 2020 22:44:38

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-08-31T17:44:34', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '5769ac60-5e30-488a-a029-23f16f3b46a5' User entered '31 Aug 2020 17:44'	System	31 Aug 2020 22:44:38
	System	31 Aug 2020 22:44:38

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 5'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:33', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8495a970-513e-4423-8341-dd743b72e33a'	System	02 Sep 2020 03:22:45
User entered 'None (0)'	System	02 Sep 2020 03:22:45

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:34', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8495a970-513e-4423-8341-dd743b72e33a'	System	02 Sep 2020 03:22:45
User entered 'None (0)'	System	02 Sep 2020 03:22:45

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:35', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8495a970-513e-4423-8341-dd743b72e33a' User entered 'None (0)'	System	02 Sep 2020 03:22:45
	System	02 Sep 2020 03:22:45



US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:37', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8495a970-513e-4423-8341-dd743b72e33a' User entered 'None (0)'	System	02 Sep 2020 03:22:45
	System	02 Sep 2020 03:22:45

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:38', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8495a970-513e-4423-8341-dd743b72e33a' User entered 'None (0)'	System	02 Sep 2020 03:22:45
	System	02 Sep 2020 03:22:45

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:39', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8495a970-513e-4423-8341-dd743b72e33a'	System	02 Sep 2020 03:22:45
User entered 'None (0)'	System	02 Sep 2020 03:22:45

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:41', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8495a970-513e-4423-8341-dd743b72e33a'	System	02 Sep 2020 03:22:45
User entered 'No (N)'	System	02 Sep 2020 03:22:45

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-01T22:22:43', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8495a970-513e-4423-8341-dd743b72e33a' User entered '01 Sep 2020 22:22'	System	02 Sep 2020 03:22:45
	System	02 Sep 2020 03:22:45

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 22:02:48

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:31:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 6'	System	28 Aug 2020 22:02:48



US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:10:56', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b28cddc6-d9de-4aaa-8214-7397e7168f46' User entered 'None (0)'	System	03 Sep 2020 03:11:13
	System	03 Sep 2020 03:11:13

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:10:58', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b28cddc6-d9de-4aaa-8214-7397e7168f46' User entered 'None (0)'	System	03 Sep 2020 03:11:13
	System	03 Sep 2020 03:11:13

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:10:59', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b28cddc6-d9de-4aaa-8214-7397e7168f46' User entered 'None (0)'	System	03 Sep 2020 03:11:13
	System	03 Sep 2020 03:11:13

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:11:00', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b28cddc6-d9de-4aaa-8214-7397e7168f46' User entered 'None (0)'	System	03 Sep 2020 03:11:13
	System	03 Sep 2020 03:11:13

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:11:03', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b28cddc6-d9de-4aaa-8214-7397e7168f46' User entered 'None (0)'	System	03 Sep 2020 03:11:13
	System	03 Sep 2020 03:11:13

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:11:05', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b28cddc6-d9de-4aaa-8214-7397e7168f46' User entered 'None (0)'	System	03 Sep 2020 03:11:13
	System	03 Sep 2020 03:11:13

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:11:07', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b28cddc6-d9de-4aaa-8214-7397e7168f46' User entered 'No (N)'	System	03 Sep 2020 03:11:13
	System	03 Sep 2020 03:11:13

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-02T22:11:10', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b28cddc6-d9de-4aaa-8214-7397e7168f46' User entered '02 Sep 2020 22:11'	System	03 Sep 2020 03:11:13
	System	03 Sep 2020 03:11:13



US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 7'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:36', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b6ba974e-c2cd-43c6-9da5-88d7f99980f9' User entered 'None (0)'	System	04 Sep 2020 02:23:51
	System	04 Sep 2020 02:23:51

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:38', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b6ba974e-c2cd-43c6-9da5-88d7f99980f9' User entered 'None (0)'	System	04 Sep 2020 02:23:51
	System	04 Sep 2020 02:23:51

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:39', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b6ba974e-c2cd-43c6-9da5-88d7f99980f9' User entered 'None (0)'	System	04 Sep 2020 02:23:51
	System	04 Sep 2020 02:23:51

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:41', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b6ba974e-c2cd-43c6-9da5-88d7f99980f9' User entered 'None (0)'	System	04 Sep 2020 02:23:51
	System	04 Sep 2020 02:23:51

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:31:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:42', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b6ba974e-c2cd-43c6-9da5-88d7f99980f9' User entered 'None (0)'	System	04 Sep 2020 02:23:51
	System	04 Sep 2020 02:23:51



**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:31:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:43', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b6ba974e-c2cd-43c6-9da5-88d7f99980f9' User entered 'None (0)'	System	04 Sep 2020 02:23:51
	System	04 Sep 2020 02:23:51

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:45', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b6ba974e-c2cd-43c6-9da5-88d7f99980f9' User entered 'No (N)'	System	04 Sep 2020 02:23:51
	System	04 Sep 2020 02:23:51

**US3862086**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:31:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-09-03T21:23:46', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'b6ba974e-c2cd-43c6-9da5-88d7f99980f9' User entered '03 Sep 2020 21:23'	System	04 Sep 2020 02:23:51
	System	04 Sep 2020 02:23:51

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 22:02:48

US3862086

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:26:27
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	04 Sep 2020 20:50:53

US3862086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:26:27
User entered '4 Sep 2020'	Chanei Henry (b) (4) (b) (4)	04 Sep 2020 20:50:53

US3862086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:26:27
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4) (b) (4)	04 Sep 2020 20:50:53



US3862086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:26:27
User entered empty.	Chanei Henry (b) (4) (b) (4)	04 Sep 2020 20:50:53

US3862086

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:26:56
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	04 Sep 2020 20:51:01

**US3862086**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'I'	System	04 Sep 2020 20:51:01

**US3862086**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:32:16
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	12 Sep 2020 00:29:00

US3862086

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:32:16
User entered '11 Sep 2020'	Chanei Henry (b) (4) (b) (4)	12 Sep 2020 00:29:00

**US3862086**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:32:16
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4) (b) (4)	12 Sep 2020 00:29:00

US3862086

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:32:16
User entered empty.	Chanei Henry (b) (4) (b) (4)	12 Sep 2020 00:29:00

US3862086

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:32:19
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	12 Sep 2020 00:29:20



**US3862086**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1'	System	12 Sep 2020 00:29:20

**US3862086**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:33:09
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	18 Sep 2020 19:01:40

US3862086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:33:09
User entered '18 Sep 2020'	Chanei Henry (b) (4) (b) (4)	18 Sep 2020 19:01:40

US3862086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:33:09
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4) (b) (4)	18 Sep 2020 19:01:40

US3862086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:33:09
User entered empty.	Chanei Henry (b) (4) (b) (4)	18 Sep 2020 19:01:40

US3862086

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:33:13
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	18 Sep 2020 19:01:45

**US3862086**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1'	System	18 Sep 2020 19:01:45

US3862086

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:33:21
User entered 'Yes (Y)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:18:57



**US3862086**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4)	29 Oct 2020 15:33:21
User entered '25 Sep 2020'	Coni Cheesman (b) (4)	07 Oct 2020 18:18:57
	(b) (4)	

US3862086

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:33:21
User entered 'Clinic (Clinic)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:18:57

**US3862086**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'VISIT2'	System	07 Oct 2020 18:18:57

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User accepted default value 'Pre-Dose (PREDOSE)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:21
User entered 'Yes (Y)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:22
User entered '25 Sep 2020'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:25
User entered '14:14'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '25 Sep 2020 14:14'	System	07 Oct 2020 18:19:53



US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:24
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 18:20:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Oct 2020 18:20:55
User entered '97.6' F reason for change: New Information	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:20:55
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 18:19:53
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:27
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	07 Oct 2020 18:21:15
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	07 Oct 2020 18:20:55
User entered 'Other (Other)' reason for change: New Coni Cheesman Information	(b) (4) (b) (4)	07 Oct 2020 18:20:55
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:28
User entered 'Temporal' reason for change: New Information	Coni Cheesman (b) (4)	07 Oct 2020 18:21:15
User entered empty.	(b) (4) Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:29
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 18:20:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Oct 2020 18:20:55
User entered '95' reason for change: New Information	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:20:55
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 18:19:53
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'bpm'	System	07 Oct 2020 18:20:55
User entered empty.	System	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:31
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 18:20:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Oct 2020 18:20:55
User entered '12' reason for change: New Information	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:20:55
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 18:19:53
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'breaths/min'	System	07 Oct 2020 18:20:55
User entered empty.	System	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:34
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 18:20:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Oct 2020 18:20:55
User entered '115' reason for change: New Information	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:20:55
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 18:19:53
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53



US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'mmHg'	System	07 Oct 2020 18:20:55
User entered empty.	System	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:33
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 18:20:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Oct 2020 18:20:55
User entered '83' reason for change: New Information	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:20:55
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 18:19:53
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'mmHg'	System	07 Oct 2020 18:20:55
User entered empty.	System	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User accepted default value 'Post-Dose (POSTDOSE)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:40
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 18:09:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 18:09:15
User entered 'No (N)' reason for change: New Information	Chanei Henry (b) (4) (b) (4)	27 Oct 2020 18:09:15
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:19:53
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:40
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:40
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	07 Oct 2020 18:19:53



US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:40
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:40
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:40
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:40
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:40
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:40
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53



US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:42:40
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	07 Oct 2020 18:19:53

US3862086

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:51:50
User entered 'Yes (Y)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:22:08

US3862086

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:51:51
User entered '25 Sep 2020'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:22:08

US3862086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:09:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:23:03

US3862086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:09:16
User entered '25 Sep 2020'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:23:03

US3862086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 16:09:18
User entered 'Urine (URINE)'	Coni Cheesman (b) (4)	07 Oct 2020 18:23:03
	(b) (4)	



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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:09:23
User closed query 'Per CDM: Site response is noted. Per Protocol Amendment 4, section 8.3.5, participants who have a positive pregnancy test any time during the study should receive no further dosing with the IP, but should remain in the study and be followed-up for safety. Please fill out the Dosing Discontinuation eCRF located in the End of Study Folder and use the last date of exposure. Thanks.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 15:09:44
Query 'Per CDM: Site response is noted. Per Protocol Amendment 4, section 8.3.5, participants who have a positive pregnancy test any time during the study should receive no further dosing with the IP, but should remain in the study and be followed-up for safety. Please fill out the Dosing Discontinuation eCRF located in the End of Study Folder and use the last date of exposure. Thanks.' answered with 'Dosing discontinuation completed' (Site from DM).	Chanei Henry (b) (4) (b) (4)	27 Oct 2020 18:09:49
Query 'Per CDM: Site response is noted. Per Protocol Amendment 4, 8.3.5, participants who have a positive pregnancy test any time during the study should receive no further dosing with the IP, but should remain in the study and be followed-up for safety. Please fill out the Dosing Discontinuation eCRF located in the End of Study Folder and use the last date of exposure. Thanks.' canceled (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:32:11
User opened query 'Per CDM: Site response is noted. Per Protocol Amendment 4, section 8.3.5, participants who have a positive pregnancy test any time during the study should receive no further dosing with the IP, but should remain in the study and be followed-up for safety. Please fill out the Dosing Discontinuation eCRF located in the End of Study Folder and use the last date of exposure. Thanks.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:32:08

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Result](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Site response is noted. Per Protocol Amendment 4, 8.3.5, participants who have a positive pregnancy test any time during the study should receive no further dosing with the IP, but should remain in the study and be followed-up for safety. Please fill out the Dosing Discontinuation eCRF located in the End of Study Folder and use the last date of exposure. Thanks.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:31:45
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 09:10:00
Query 'PV Query: Please send pregnancy report form to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:18:40
User opened query 'PV Query: Please send pregnancy report form to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:12:42
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'Confirm pregnancy test as positive. Pregnancy form has been submitted to IQVIA' (Site from System).	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:24:27
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	07 Oct 2020 18:23:03
User entered 'Positive (POSITIVE)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:23:03

US3862086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:09:24
DataPoint Un-verified.		11 Nov 2020 18:10:42
DataPoint Verified.		11 Nov 2020 18:10:23
User entered 'No (N)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:23:03

US3862086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:09:26
DataPoint Un-verified.		11 Nov 2020 18:10:44
DataPoint Verified.		11 Nov 2020 18:10:25
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:23:03

US3862086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:55

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:09:27
DataPoint Un-verified.		11 Nov 2020 18:10:46
DataPoint Verified.		11 Nov 2020 18:10:27
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:23:03

**US3862086**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	07 Oct 2020 18:23:03

US3862086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:55:26
User entered 'No (N)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:01

US3862086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:55:26
User entered 'Pregnancy (PREGNANCY)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:01



US3862086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:55:26
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:01

US3862086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	07 Oct 2020 18:25:01

US3862086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4)	29 Oct 2020 15:55:26
User entered empty.	Coni Cheesman (b) (4)	07 Oct 2020 18:25:01
	(b) (4)	

US3862086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:55:26
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:01

US3862086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	07 Oct 2020 18:25:01

US3862086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:55:26
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:01

US3862086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		29 Oct 2020 15:55:26
User entered empty.	System	07 Oct 2020 18:25:01

US3862086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	07 Oct 2020 18:25:01



US3862086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:59:58
User entered 'Yes (Y)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:28

US3862086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:59:58
User entered '25 Sep 2020'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:28

US3862086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:59:58
User entered '16:03'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:28

US3862086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '25 Sep 2020 16:03'	System	07 Oct 2020 18:25:28

US3862086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:31:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:00:05
User entered '25 Sep 2020'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:54

US3862086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:54

US3862086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:00:05
User entered 'No (N)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:54

US3862086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:00:05
User entered empty.	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:54



**US3862086**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	07 Oct 2020 18:25:54

US3862086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:54

US3862086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:00:05
User entered 'Yes (Y)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:54

US3862086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:00:05
User entered '15:42'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:25:54

**US3862086**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '25 Sep 2020 15:42'	System	07 Oct 2020 18:25:54

US3862086

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:01:30
User entered 'Yes (Y)'	Coni Cheesman (b) (4) (b) (4)	07 Oct 2020 18:26:17

**US3862086**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1'	System	07 Oct 2020 18:26:17

**US3862086**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:13:38
User entered 'Yes (Y)'	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:19:53



US3862086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
	(b) (4)	
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Nov 2020 20:13:56
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Nov 2020 20:08:39
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:13:38
User entered '7 Oct 2020'	Coni Cheesman (b) (4)	10 Oct 2020 19:19:53
	(b) (4)	

US3862086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:13:38
User entered 'Contact Made (CONTACT MADE)'	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:19:53

US3862086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:13:38
User entered 'Day 36 Contact made outside of window.'	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:19:53

US3862086

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:14:32
User entered 'Yes (Y)'	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:20:07

US3862086

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1'	System	10 Oct 2020 19:20:07

US3862086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:14:39
User entered 'Yes (Y)'	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:20:21

US3862086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
	(b) (4)	
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Nov 2020 20:13:56
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Nov 2020 20:08:39
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:14:39
User entered '10 Oct 2020'	Coni Cheesman (b) (4)	10 Oct 2020 19:20:21
	(b) (4)	

US3862086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:14:39
User entered 'Contact Made (CONTACT MADE)'	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:20:21



US3862086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:14:39
User entered empty.	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:20:21

US3862086

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:14:42
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	19 Oct 2020 20:49:26

**US3862086**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'I'	System	19 Oct 2020 20:49:26

US3862086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:06:52
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	11 Nov 2020 20:06:43

US3862086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:06:52
User entered '19 Oct 2020'	Sandra Francisco (b) (4) (b) (4)	11 Nov 2020 20:06:43

US3862086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:06:52
User entered 'Contact Not Made (CONTACT NOT MADE)'	Sandra Francisco (b) (4) (b) (4)	11 Nov 2020 20:06:43

US3862086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:06:52
User entered 'Contact was attempted once on 16OCT2020 and twice on 19OCT2020. Subject was not reachable.'	Sandra Francisco (b) (4) (b) (4)	11 Nov 2020 20:06:43

US3862086

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:06:55
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:33



**US3862086**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'I'	System	21 Nov 2020 01:32:33

US3862086

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:02
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:41

**US3862086**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:02
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:41

**US3862086**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:02
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:41

**US3862086**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'VISIT3'	System	21 Nov 2020 01:32:41

US3862086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:10
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:49

US3862086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:10
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:49

US3862086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:10
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:49



**US3862086**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	21 Nov 2020 01:32:49

US3862086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:10
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:49

US3862086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:10
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:49

**US3862086**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:10
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:49

US3862086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:10
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:49

**US3862086**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	21 Nov 2020 01:32:49

US3862086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:10
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:49

**US3862086**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:55**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	21 Nov 2020 01:32:49



US3862086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:10
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:49

US3862086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	21 Nov 2020 01:32:49

US3862086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:10
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:49

US3862086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	21 Nov 2020 01:32:49

**US3862086**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:55**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:14
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:53

US3862086

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:14
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:53



US3862086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:17
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:58

US3862086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:17
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:58

US3862086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:07:17
User entered empty.	Chanei Henry (b) (4) (b) (4)	21 Nov 2020 01:32:58

**US3862086**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	21 Nov 2020 01:32:58

US3862086

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:19:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:38:54
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	10 Dec 2020 21:37:57

**US3862086**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1'	System	10 Dec 2020 21:37:57

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 64'	System	28 Aug 2020 22:02:48

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39



US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39



**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39



**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39



**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39
Data entry locked.	System	28 Aug 2020 22:02:48
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 22:02:48

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39
Data entry locked.	System	28 Aug 2020 22:02:48
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 22:02:48

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 71'	System	28 Aug 2020 22:02:48

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39



**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39



**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39



**US3862086**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

US3862086

Folder: Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

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Audit	User	Time (GMT)
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

US3862086

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39
Data entry locked.	System	28 Aug 2020 22:02:48
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 22:02:48

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:18:31
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39
Data entry locked.	System	28 Aug 2020 22:02:48
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 22:02:48

**US3862086**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39
Data entry locked.	System	28 Aug 2020 22:02:48
User entered 'Day 78'	System	28 Aug 2020 22:02:48

US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-11-13T12:32:50', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '9601c696-1d1d-4e85-88b2-33a49398d8ea'	System	13 Nov 2020 18:33:02
User entered 'No (N)'	System	13 Nov 2020 18:33:02
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39



US3862086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-11-13T12:32:54', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '9601c696-1d1d-4e85-88b2-33a49398d8ea'	System	13 Nov 2020 18:33:02
User entered 'No (N)'	System	13 Nov 2020 18:33:02
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:31:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-11-13T12:32:58', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '9601c696-1d1d-4e85-88b2-33a49398d8ea' User entered '13 Nov 2020 12:32:58'	System	13 Nov 2020 18:33:02
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39

**US3862086**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39
Data entry locked.	System	28 Aug 2020 22:02:48
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 22:02:48

**US3862086**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:16:52
DataPoint Activated.	System	06 Nov 2020 20:13:56
DataPoint Inactivated.	System	06 Nov 2020 20:08:39
Data entry locked.	System	28 Aug 2020 22:02:48
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 22:02:48

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56



US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56



US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56



**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 20:18:31



**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:18:31

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56



US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56



**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56



**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:18:31

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-12-10T15:30:21', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '7683e93d-6ebb-4926-8571-3a92fbe138cd' User entered 'No (N)'	System	10 Dec 2020 21:30:52
	System	10 Dec 2020 21:30:52

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-12-10T15:30:31', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '7683e93d-6ebb-4926-8571-3a92fbe138cd' User entered 'Yes (Y)'	System	10 Dec 2020 21:30:52
	System	10 Dec 2020 21:30:52

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-12-10T15:30:37', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '7683e93d-6ebb-4926-8571-3a92fbe138cd' User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Dec 2020 21:30:52



**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-12-10T15:30:43', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '7683e93d-6ebb-4926-8571-3a92fbe138cd' User entered '10 Dec 2020 15:30:43'	System	10 Dec 2020 21:30:52
	System	10 Dec 2020 21:30:52

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:18:31

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-12-16T18:08:36', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'bd7796e1-7146-4ffd-83ec-52da2fda0670'	System	17 Dec 2020 00:08:44
User entered 'No (N)'	System	17 Dec 2020 00:08:44

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-12-16T18:08:39', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'bd7796e1-7146-4ffd-83ec-52da2fda0670'	System	17 Dec 2020 00:08:44
User entered 'No (N)'	System	17 Dec 2020 00:08:44

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-12-16T18:08:42', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'bd7796e1-7146-4ffd-83ec-52da2fda0670' User entered '16 Dec 2020 18:08:42'	System	17 Dec 2020 00:08:44
	System	17 Dec 2020 00:08:44

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 20:18:31



**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:18:31

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-12-22T12:00:10', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8eba31b2-5018-4d6b-ae37-e20c3296a801' User entered 'No (N)'	System	22 Dec 2020 18:00:21
	System	22 Dec 2020 18:00:21

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-12-22T12:00:13', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8eba31b2-5018-4d6b-ae37-e20c3296a801'	System	22 Dec 2020 18:00:21
User entered 'No (N)'	System	22 Dec 2020 18:00:21

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-12-22T12:00:15', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '8eba31b2-5018-4d6b-ae37-e20c3296a801' User entered '22 Dec 2020 12:00:15'	System	22 Dec 2020 18:00:21
	System	22 Dec 2020 18:00:21

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:18:31



US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-12-31T12:09:42', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'c62f20c2-b24d-4b9d-bd77-d8f3d1d61b21' User entered 'No (N)'	System	31 Dec 2020 20:33:33
	System	31 Dec 2020 20:33:33

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-12-31T12:09:44', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'c62f20c2-b24d-4b9d-bd77-d8f3d1d61b21' User entered 'No (N)'	System	31 Dec 2020 20:33:33
	System	31 Dec 2020 20:33:33

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2020-12-31T12:09:46', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: 'c62f20c2-b24d-4b9d-bd77-d8f3d1d61b21' User entered '31 Dec 2020 12:09:46'	System	31 Dec 2020 20:33:33
	System	31 Dec 2020 20:33:33

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:18:31

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2021-01-03T08:27:50', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '418cc450-4586-49a8-a217-23fa028be147' User entered 'No (N)'	System	03 Jan 2021 15:27:57
	System	03 Jan 2021 15:27:57

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2021-01-03T08:27:52', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '418cc450-4586-49a8-a217-23fa028be147'	System	03 Jan 2021 15:27:57
User entered 'No (N)'	System	03 Jan 2021 15:27:57



**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2021-01-03T08:27:54', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '418cc450-4586-49a8-a217-23fa028be147' User entered '03 Jan 2021 08:27:54'	System	03 Jan 2021 15:27:57
	System	03 Jan 2021 15:27:57

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:18:31

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56



US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56



**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56



**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:18:31



**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2021-01-19T12:00:13', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '3de2b65a-5c62-4baa-bd92-947def85298f' User entered 'No (N)'	System	19 Jan 2021 18:00:41
	System	19 Jan 2021 18:00:41

US3862086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2021-01-19T12:00:16', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '3de2b65a-5c62-4baa-bd92-947def85298f' User entered 'No (N)'	System	19 Jan 2021 18:00:41
	System	19 Jan 2021 18:00:41

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D2B3D7E-8C91-4CF5-B876-C87257F61631)', Time: '2021-01-19T12:00:19', User OID: 'PatientReportedOutcome (US3862086)', ODM File OID: '3de2b65a-5c62-4baa-bd92-947def85298f' User entered '19 Jan 2021 12:00:19'	System	19 Jan 2021 18:00:41
	System	19 Jan 2021 18:00:41

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:18:31
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 20:18:31

**US3862086**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 14:43:50
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:28:35
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4) (b) (4)	17 Dec 2020 22:00:22

US3862086

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 14:43:50
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:28:35
User entered '20 Nov 2020'	(b) (4) Shetel Anassi (b) (4) (b) (4)	17 Dec 2020 22:00:22

**US3862086**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 14:43:50
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:28:35
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Shetel Anassi (b) (4) (b) (4)	17 Dec 2020 22:00:22



US3862086

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 14:43:50
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:28:35
User entered 'Technical issues with subject device'	(b) (4) Shetel Anassi (b) (4) (b) (4)	17 Dec 2020 22:00:22

US3862086

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 14:43:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
User entered 'Yes (Y)'	(b) (4)	
	Shetel Anassi (b) (4)	24 Mar 2021 21:47:08
	(b) (4)	

**US3862086**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered 'I'	System	24 Mar 2021 21:47:08

**US3862086**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 14:44:02
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
User entered 'Yes (Y)'	(b) (4)	
	Shetel Anassi (b) (4)	25 Mar 2021 18:45:42
	(b) (4)	

**US3862086**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:55**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 14:44:02
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
User entered '10 Dec 2020'	(b) (4)	
	Shetel Anassi (b) (4)	25 Mar 2021 18:45:42
	(b) (4)	

US3862086

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 14:44:02
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Shetel Anassi (b) (4) (b) (4)	25 Mar 2021 18:45:42

**US3862086**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 14:44:02
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
User entered empty.	Shetel Anassi (b) (4)	25 Mar 2021 18:45:42
	(b) (4)	

US3862086

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 14:44:07
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	25 Mar 2021 18:45:55
	(b) (4)	
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	24 Mar 2021 21:47:23
	(b) (4)	



**US3862086**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	25 Mar 2021 18:45:55
User entered 'I'	System	24 Mar 2021 21:47:23

US3862086

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

Form: Visit Date

Generated On: 12 Aug 2021 13:31:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 15:46:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 May 2021 15:13:30
DataPoint Verified.		16 Apr 2021 19:23:05
DataPoint Un-verified.		14 Apr 2021 15:21:10
DataPoint Verified.		14 Apr 2021 15:14:13
Query 'Data is required. Please complete.' answered with 'to be eliminated by (b) (6) . subject has been dc/ed.' (Site from System).	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:12:01
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 19:11:29
DataPoint Un-verified.	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:11:29
Signature has been broken.	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:11:29
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:11:29
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 17:24:20
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:17:16
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	31 Mar 2021 18:27:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:12:04
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 15:55:25

US3862086

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

Form: Visit Date

Generated On: 12 Aug 2021 13:31:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
DataPoint Verified.		02 Apr 2021 17:24:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	31 Mar 2021 18:27:08
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:12:04
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 15:55:25

US3862086

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

Form: Visit Date

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
DataPoint Verified.		02 Apr 2021 17:24:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
User entered empty.	(b) (4) Sandra Francisco (b) (4)	31 Mar 2021 18:27:08
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:12:04
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 15:55:25

US3862086

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

Form: Visit Date

Generated On: 12 Aug 2021 13:31:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
User entered empty.	System	12 Apr 2021 19:11:29
User entered 'UNBLND_DECIDE'	System	31 Mar 2021 18:27:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:12:04
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 15:55:25

US3862086

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:55

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
User closed query 'Per CDM Re-Query: Please confirm if new informed consent was signed during unblinding visit under Amendment 6. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 11:24:12
Query 'Per CDM Re-Query: Please confirm if new informed consent was signed during unblinding visit under Amendment 6. Thank you.' answered with 'no informed consent updated since subject was remotely discontinued. Subject did not come to site' (Site from DM).		19 Apr 2021 19:10:30
User opened query 'Per CDM Re-Query: Please confirm if new informed consent was signed during unblinding visit under Amendment 6. Thank you.' (Site from DM).		16 Apr 2021 13:38:33
User closed query 'Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).		16 Apr 2021 13:38:33
Query 'Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' answered with 'DISCONTINUED UNDER AMENDMENT 6, THEN RECEIVED VACCINE ELSEWHERE.' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:21:42
User opened query 'Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 08:04:06
DataPoint Verified.		02 Apr 2021 17:24:12

US3862086

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:55

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	30 Mar 2021 18:30:00
	(b) (4)	

**US3862086**

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

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:31:55**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
DataPoint Verified.		02 Apr 2021 17:24:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
	(b) (4)	
User entered '0'	Sandra Francisco (b) (4)	30 Mar 2021 18:30:00
	(b) (4)	



US3862086

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:55

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
DataPoint Verified.		02 Apr 2021 17:24:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	30 Mar 2021 18:30:00
	(b) (4)	

US3862086

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:55

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
User closed query 'Per CDM, per Sponsor Review: IRT/EDC reports subject was unblinded under Amendment 5, but Unblinding form is either blank or states 'Unblinded under A6 or later'. Please update data as appropriate on this field of Unblinding form.' (Site from DM).		29 Apr 2021 20:57:51
Query 'Per CDM, per Sponsor Review: IRT/EDC reports subject was unblinded under Amendment 5, but Unblinding form is either blank or states 'Unblinded under A6 or later'. Please update data as appropriate on this field of Unblinding form.' answered with 'DISCONTINUED UNDER AMENDMENT 6, THEN RECEIVED VACCINE ELSEWHERE.' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:21:39
User opened query 'Per CDM, per Sponsor Review: IRT/EDC reports subject was unblinded under Amendment 5, but Unblinding form is either blank or states 'Unblinded under A6 or later'. Please update data as appropriate on this field of Unblinding form.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 19:25:01
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 17:24:12
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:17:16
User entered 'Amendment 6 or later (Amendment 6 or later)'	Sandra Francisco (b) (4) (b) (4)	30 Mar 2021 18:30:00

US3862086

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:55

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
DataPoint Verified.		02 Apr 2021 17:24:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
	(b) (4)	
User entered '14 Jan 2021'	Sandra Francisco (b) (4)	30 Mar 2021 18:30:00
	(b) (4)	

US3862086

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:55

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
DataPoint Verified.		02 Apr 2021 17:24:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
	(b) (4)	
User entered 'Placebo (Placebo)'	Sandra Francisco (b) (4)	30 Mar 2021 18:30:00
	(b) (4)	

US3862086

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:55

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
DataPoint Verified.		02 Apr 2021 17:24:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
	(b) (4)	
User entered 'Placebo (Placebo)'	Sandra Francisco (b) (4)	30 Mar 2021 18:30:00
	(b) (4)	

US3862086

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:55

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
DataPoint Verified.		02 Apr 2021 17:24:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
	(b) (4)	
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	30 Mar 2021 18:41:04
	(b) (4)	
User entered 'Placebo (Placebo)'	Sandra Francisco (b) (4)	30 Mar 2021 18:30:00
	(b) (4)	

US3862086

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:55

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
DataPoint Verified.		02 Apr 2021 17:24:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	30 Mar 2021 18:30:00
	(b) (4)	

**US3862086**

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

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:31:55**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
User entered '1'	System	30 Mar 2021 18:30:00



US3862086

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:55

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
User entered empty.	System	30 Mar 2021 18:30:00

US3862086

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:18
DataPoint Verified.		14 Apr 2021 15:13:38
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 21:51:17
Query 'Data is required. Please complete.' answered with 'to be eliminated by (b) (6) . subject has been dc/ed.' (Site from System).	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:11:50
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 19:11:35
DataPoint Un-verified.	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:11:35
Signature has been broken.	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:11:35
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:11:35
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 17:23:57
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:17:16
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	31 Mar 2021 18:27:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:04:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 15:54:02

US3862086

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
DataPoint Verified.		02 Apr 2021 17:23:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	31 Mar 2021 18:27:43
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:04:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 15:54:02

US3862086

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
DataPoint Verified.		02 Apr 2021 17:23:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	31 Mar 2021 18:27:43
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:04:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 15:54:02

US3862086

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
User entered empty.	System	31 Mar 2021 18:27:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:04:57
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 15:54:02

US3862086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:31:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:13:45
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 21:51:21
Query 'Data is required. Please complete.' answered with 'to be eliminated by (b) (6) . subject has been dc/ed.' (Site from System).	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:11:57
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 19:11:54
DataPoint Un-verified.	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:11:54
Signature has been broken.	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:11:54
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4) (b) (4)	12 Apr 2021 19:11:54
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 17:23:51
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:17:16
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	31 Mar 2021 18:27:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:04:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 15:54:11

US3862086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:31:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
DataPoint Verified.		02 Apr 2021 17:23:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
User entered empty.	(b) (4) Sandra Francisco (b) (4)	31 Mar 2021 18:27:47
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:04:49
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 15:54:11

US3862086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:31:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
DataPoint Verified.		02 Apr 2021 17:23:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	31 Mar 2021 18:27:47
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:04:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 15:54:11



US3862086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:31:55

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:06
User entered empty.	System	31 Mar 2021 18:27:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:04:49
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 15:54:11

US3862086

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:31:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:22:23
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:14:45
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sandra Francisco	(b) (4) 07 Dec 2020 19:49:21
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco	(b) (4) 30 Nov 2020 18:31:39
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
User closed query 'Per source, mifepristone and misoprostol are reported for elective termination of pregnancy. Please enter in EDC.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:02:41
Query 'Per source, mifepristone and misoprostol are reported for elective termination of pregnancy. Please enter in EDC.' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	16 Nov 2020 16:25:32
User opened query 'Per source, mifepristone and misoprostol are reported for elective termination of pregnancy. Please enter in EDC.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:09:51
User closed query 'Source has listed PCN and Ribavirin as drug allergies. Please also consider adding Alprazolam and Zolpidem to Concomitant Medication page. Please update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 22:37:25
Query 'Source has listed PCN and Ribavirin as drug allergies. Please also consider adding Alprazolam and Zolpidem to Concomitant Medication page. Please update EDC accordingly. ' answered with 'data updated' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:33:52
User opened query 'Source has listed PCN and Ribavirin as drug allergies. Please also consider adding Alprazolam and Zolpidem to Concomitant Medication page. Please update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:29:26
Query 'Source has listed PCN and Ribavirin as drug allergies. Please update EDC. ' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:27:19
User opened query 'Source has listed PCN and Ribavirin as drug allergies. Please update EDC. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:20:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:15:21
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:42:34

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:22:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:04:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:04:49
Data point term sent to Coder	System	01 Sep 2020 16:03:20
Coding entries removed.	Trent Davis (b) (4) (b) (4)	01 Sep 2020 16:02:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS FOR SYSTEMIC USE, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:46:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:46:39
Data point term sent to Coder	System	31 Aug 2020 19:45:10
User entered 'Albuterol'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:22:23
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:22:24
User entered 'Asthma'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:22:19
User closed query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 puff." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 04:40:38
Query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 puff." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Dose identified as 90mcg/inhalation as needed ' (Site from DM).	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 18:30:53
User entered '90' reason for change: Per Query Resolution	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 18:30:00
User opened query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 puff." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:02:14
User entered '1'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:39:52
User closed query 'Please consider updating dose unit to mcg per source. Please update EDC accordingly. ' (Site from CRA).		09 Nov 2020 22:39:50
Query 'Please consider updating dose unit to mcg per source. Please update EDC accordingly. ' answered with 'Data corrected' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:31:12
User opened query 'Please consider updating dose unit to mcg per source. Please update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:22:13
User entered 'ug (ug)' reason for change: Per Query Resolution	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 18:30:00
User entered 'puff (PUFF)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50



US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:22:15
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:22:18
User entered 'as needed (PRN)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:22:26
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:22:27
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	01 Sep 2020 16:02:34
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:22:29
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:22:40
User closed query 'Per DM CLR: Please confirm if this Con Med was given for MH #1. If yes, please note that Con Med start date (UN UNK 2010) is prior to the start date of the corresponding MH (UN UNK 2012). Review and reconcile the Con Med and MH start dates and correct as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 16:09:23
Query 'Per DM CLR: Please confirm if this Con Med was given for MH #1. If yes, please note that Con Med start date (UN UNK 2010) is prior to the start date of the corresponding MH (UN UNK 2012). Review and reconcile the Con Med and MH start dates and correct as appropriate.' answered with 'Date clarified and amended' (Site from DM).	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 18:31:44
User entered 'UN UNK 2012' reason for change: Data Entry Error	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 18:31:16
User opened query 'Per DM CLR: Please confirm if this Con Med was given for MH #1. If yes, please note that Con Med start date (UN UNK 2010) is prior to the start date of the corresponding MH (UN UNK 2012). Review and reconcile the Con Med and MH start dates and correct as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:02:47
User entered 'un UNK 2010'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:31:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:22:41
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:22:43
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50



US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:22:44
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:22:46
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:44:50

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:31:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 19:44:50

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:31:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 19:44:50

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:31:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	31 Aug 2020 19:44:50

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:48:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:48:38
Data point term sent to Coder	System	31 Aug 2020 19:48:14
User entered 'Venlafaxine'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered 'Depression'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03



US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered '225'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered 'un Jul 2019'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03



US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:31:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:23:08
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:48:03

US3862086

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:31:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1'	System	31 Aug 2020 19:48:03

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:31:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1'	System	31 Aug 2020 19:48:03

US3862086

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:31:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '804 (804)'	System	31 Aug 2020 19:48:03

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:51:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:51:37
Data point term sent to Coder	System	31 Aug 2020 19:50:19
User entered 'Zyrtec'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43



US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered 'Seasonal Allergies'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered '10'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43



US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered 'un Mar 2019'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:24:16
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:49:43

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:31:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1'	System	31 Aug 2020 19:49:43

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:31:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1'	System	31 Aug 2020 19:49:43



US3862086

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:31:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '804 (804)'	System	31 Aug 2020 19:49:43

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
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: LANSOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:53:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:53:39
Data point term sent to Coder	System	31 Aug 2020 19:52:23
User entered 'Lansoprazole'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered 'Gastroesophageal Reflux Disease'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered '15'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28



US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered 'UN UNK 2020'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered '0'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered empty.	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:27:02
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	31 Aug 2020 19:51:28



US3862086

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:31:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1'	System	31 Aug 2020 19:51:28

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:31:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '1'	System	31 Aug 2020 19:51:28

US3862086

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:31:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered '804 (804)'	System	31 Aug 2020 19:51:28

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTERONE RECEPTOR MODULATORS, PRODUCT: MIFEPRISTONE - version WHODrug-Global-B3\\202003.	(b) (4) Cordero Import (b) (4) (b) (4)	06 Nov 2020 20:26:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:26:27
Data point term sent to Coder	System	06 Nov 2020 20:25:54
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:25:15
Data point term sent to Coder	System	06 Nov 2020 20:11:22
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:11:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTERONE RECEPTOR MODULATORS, PRODUCT: MIFEPRISTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Oct 2020 05:17:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Oct 2020 05:17:17
Data point term sent to Coder	System	10 Oct 2020 19:22:36
User entered 'Mifepristone'	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:22:12

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered 'No (N)'	Coni Cheesman (b) (4)	10 Oct 2020 19:22:12
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 09:52:57
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'the medication was taken per the subject's decision to end the pregnancy and that all pregnancy details have already been reported accordingly to the Safety team' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	30 Nov 2020 19:55:24
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 10:32:55
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:25:15
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:11:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered 'Elective termination of pregnancy'	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:22:12

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered '200'	Coni Cheesman (b) (4)	10 Oct 2020 19:22:12
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered 'mg (mg)'	Coni Cheesman (b) (4)	10 Oct 2020 19:22:12
	(b) (4)	



US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered empty.	Coni Cheesman (b) (4)	10 Oct 2020 19:22:12
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered 'once (ONCE)'	Coni Cheesman (b) (4)	10 Oct 2020 19:22:12
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered empty.	Coni Cheesman (b) (4)	10 Oct 2020 19:22:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered 'Oral (ORAL)'	Coni Cheesman (b) (4)	10 Oct 2020 19:22:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint activated with code reason code Data required.	(b) (4)	
	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered empty.	Coni Cheesman (b) (4)	10 Oct 2020 19:22:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint activated with code reason code Data required.	(b) (4) Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	06 Nov 2020 20:11:01
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:11:01
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Nov 2020 20:08:39
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered '8 Oct 2020'	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:22:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint activated with code reason code Data required.	(b) (4)	
	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered '0'	Coni Cheesman (b) (4)	10 Oct 2020 19:22:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered 'No (N)'	Coni Cheesman (b) (4)	10 Oct 2020 19:22:12
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint activated with code reason code Data required.	(b) (4) Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	06 Nov 2020 20:11:01
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:11:01
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Nov 2020 20:08:39
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered '8 Oct 2020'	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:22:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:45
User entered 'No (N)'	Coni Cheesman (b) (4)	10 Oct 2020 19:22:12
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
User entered empty.	System	10 Oct 2020 19:22:12

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
User entered empty.	System	10 Oct 2020 19:22:12

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:15
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Shetel Anassi (b) (4)	06 Nov 2020 20:11:01
	(b) (4)	
User entered empty.	System	10 Oct 2020 19:22:12

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: UTEROTONICS, ATC: PROSTAGLANDINS, PRODUCT: MISOPROSTOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Nov 2020 20:26:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:26:26
Data point term sent to Coder	System	06 Nov 2020 20:25:53
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
Data point term sent to Coder	System	06 Nov 2020 20:11:22
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: UTEROTONICS, ATC: PROSTAGLANDINS, PRODUCT: MISOPROSTOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Oct 2020 05:17:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Oct 2020 05:17:17
Data point term sent to Coder	System	10 Oct 2020 19:23:38
User entered 'Misoprostol'	Coni Cheesman (b) (4)	10 Oct 2020 19:23:26

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered 'No (N)'	Coni Cheesman (b) (4)	10 Oct 2020 19:23:26
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered 'Elective termination of pregnancy'	Coni Cheesman (b) (4)	10 Oct 2020 19:23:26
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered '800'	Coni Cheesman (b) (4)	10 Oct 2020 19:23:26
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint activated with code reason code Data required.	(b) (4)	
	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered 'ug (ug)'	Coni Cheesman (b) (4)	10 Oct 2020 19:23:26
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered empty.	Coni Cheesman (b) (4)	10 Oct 2020 19:23:26
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered 'once (ONCE)'	Coni Cheesman (b) (4)	10 Oct 2020 19:23:26
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint activated with code reason code Data required.	(b) (4)	
	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered empty.	Coni Cheesman (b) (4)	10 Oct 2020 19:23:26
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered 'Other (OTHER)'	Coni Cheesman (b) (4)	10 Oct 2020 19:23:26
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered 'Buccally'	Coni Cheesman (b) (4)	10 Oct 2020 19:23:26
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint activated with code reason code Data required.	(b) (4)	
	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
	(b) (4)	
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Nov 2020 20:11:10
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Nov 2020 20:08:39
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered '9 Oct 2020'	Coni Cheesman (b) (4)	10 Oct 2020 19:23:26
	(b) (4)	



US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered '0'	Coni Cheesman (b) (4)	10 Oct 2020 19:23:26
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered 'No (N)'	Coni Cheesman (b) (4)	10 Oct 2020 19:23:26
	(b) (4)	

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint activated with code reason code Data required.	(b) (4) Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	06 Nov 2020 20:11:10
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:11:10
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Nov 2020 20:08:39
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered '9 Oct 2020'	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:23:26

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint activated with code reason code Data required.	(b) (4) Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
DataPoint inactivated with code reason code Data not required.	(b) (4) Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:30:50
User entered 'No (N)'	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:23:26

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
User entered empty.	System	10 Oct 2020 19:23:26

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
	(b) (4)	
User entered empty.	System	10 Oct 2020 19:23:26

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	06 Nov 2020 20:25:19
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:11:10
User entered empty.	System	10 Oct 2020 19:23:26

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Nov 2020 18:14:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 18:14:46
Data point term sent to Coder	System	13 Nov 2020 18:13:56
Coding entries removed.	Shetel Anassi (b) (4) (b) (4)	13 Nov 2020 18:13:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:03:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 06:58:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 06:58:27
Data point term sent to Coder	System	06 Nov 2020 19:42:44
User entered 'zolpidem'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47



US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:04:02
User entered 'No (N)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 03:22:24
User closed query 'Please only list one indication from medical history. As this medication is primarily prescribed for insomnia, please consider updating to insomnia only.' (Site from CRA).		16 Nov 2020 03:22:21
Query 'Please only list one indication from medical history. As this medication is primarily prescribed for insomnia, please consider updating to insomnia only.' answered with 'updated' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	13 Nov 2020 18:13:41
User entered 'INSOMNIA' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	13 Nov 2020 18:13:36
User opened query 'Please only list one indication from medical history. As this medication is primarily prescribed for insomnia, please consider updating to insomnia only.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:05:21
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:04:47
DataPoint Verified.		11 Nov 2020 18:04:04
User entered 'anxiety and insomnia'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:31:55**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:05:35
User entered '5'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:05:37
User entered 'mg (mg)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:05:41
User entered empty.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:05:43
User entered 'as needed (PRN)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered empty.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:05:47
User entered 'Oral (ORAL)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47



US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:05:49
User entered empty.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:05:54
User entered 'un Jul 2019'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:05:55
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:31:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:05:57
User entered 'Yes (Y)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:05:59
User entered empty.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:06:02
User entered 'No (N)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:41:47

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:31:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 19:41:47

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:31:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 19:41:47



US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 19:41:47

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:06:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 19:47:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 19:47:22
Data point term sent to Coder	System	06 Nov 2020 19:46:49
User entered 'alprazolam'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:06:57
User entered 'No (N)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:02:35
User entered 'Anxiety and insomnia'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:07:22
User entered '.25'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:07:24
User entered 'mg (mg)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:07:25
User entered empty.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:07:28
User entered 'as needed (PRN)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55



US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:07:29
User entered empty.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:07:31
User entered 'Oral (ORAL)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:07:33
User entered empty.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:07:35
User entered 'un Jul 2019'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:07:40
User entered '0'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:31:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:07:44
User entered 'Yes (Y)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:07:45
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	06 Nov 2020 19:46:04
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:46:04
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	06 Nov 2020 19:45:55
User entered 'un Jul 2019'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55

US3862086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:07:47
User entered 'No (N)'	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 19:45:55



**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:31:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 19:45:55

**US3862086**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:31:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 19:45:55

US3862086

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:31:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User entered empty.	System	06 Nov 2020 19:45:55

US3862086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:31:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:23:42
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
User closed query 'Please update to No, as no procedures are reported.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:53:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	30 Nov 2020 18:42:30
Query 'Please update to No, as no procedures are reported.' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	17 Nov 2020 17:15:34
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	17 Nov 2020 17:15:28
User opened query 'Please update to No, as no procedures are reported.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:09:00
User entered 'Yes (Y)'	Coni Cheesman (b) (4) (b) (4)	10 Oct 2020 19:29:37

US3862086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:31:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:23:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	30 Nov 2020 18:40:41
	(b) (4)	
User closed query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Nov 2020 20:10:27
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:10:27
	(b) (4)	
User opened query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Nov 2020 20:08:39
User entered '8 Oct 2020'	Coni Cheesman (b) (4)	10 Oct 2020 19:30:37
	(b) (4)	

US3862086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:31:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:23:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	30 Nov 2020 18:40:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:10:27
	(b) (4)	
User entered 'Elective medical termination of intrauterine pregnancy'	Coni Cheesman (b) (4)	10 Oct 2020 19:30:37
	(b) (4)	

US3862086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:31:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:23:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	30 Nov 2020 18:40:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:10:27
	(b) (4)	
User entered 'Other (OTHER)'	Coni Cheesman (b) (4)	10 Oct 2020 19:30:37
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:31:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:23:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Shetel Anassi (b) (4)	30 Nov 2020 18:40:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Shetel Anassi (b) (4)	06 Nov 2020 20:10:27
	(b) (4)	
User entered 'Pregnancy'	Coni Cheesman (b) (4)	10 Oct 2020 19:30:37
	(b) (4)	



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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:31:55

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.	(b) (4)	02 Apr 2021 17:17:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Apr 2021 13:54:28
Signature has been broken.	(b) (4), (b) (6)	
	Sandra Francisco (b) (4)	30 Mar 2021 18:41:25
	(b) (4)	
User entered '25 Sep 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	30 Mar 2021 18:41:25
User signature succeeded.	(b) (4)	
	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'N/A' (Site from System).	Shetel Anassi (b) (4)	25 Mar 2021 18:48:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	25 Mar 2021 18:48:26
	Shetel Anassi (b) (4)	25 Mar 2021 18:48:26
	(b) (4)	
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	25 Mar 2021 18:48:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 16:09:13
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:20:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 20:20:29
User entered '25 Sep 2020' reason for change: Data Entry Error	Shetel Anassi (b) (4)	06 Nov 2020 20:20:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:13:26
DataPoint Un-verified.	System	
	Shetel Anassi (b) (4)	06 Nov 2020 20:13:26
	(b) (4)	
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	06 Nov 2020 20:13:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 15:55:14
User entered '25 Sep 2020'	Chanei Henry (b) (4)	27 Oct 2020 18:08:06
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:31:55

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.	(b) (4)	02 Apr 2021 17:17:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:17:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:54:30
Signature has been broken.	Sandra Francisco (b) (4)	30 Mar 2021 18:41:25
User entered 'Pregnancy (PREGNANCY)' reason for change: Data Entry Error	(b) (4) Sandra Francisco (b) (4)	30 Mar 2021 18:41:25
User signature succeeded.	(b) (4) Thea Marie Cordero	29 Mar 2021 14:02:02
Query 'Data is required. Please complete.' answered with 'N/A' (Site from System).	(b) (4) Shetel Anassi (b) (4)	25 Mar 2021 18:48:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	25 Mar 2021 18:48:26
DataPoint Un-verified.	Shetel Anassi (b) (4) (b) (4)	25 Mar 2021 18:48:26
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	25 Mar 2021 18:48:26
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:09:14
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:20:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 20:20:29
User entered 'Pregnancy (PREGNANCY)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:20:29
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:13:26
DataPoint Un-verified.	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:13:26
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 20:13:26
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:55:14
User entered 'Pregnancy (PREGNANCY)'	Chanei Henry (b) (4) (b) (4)	27 Oct 2020 18:08:06

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:55:14
User entered empty.	Chanei Henry (b) (4) (b) (4)	27 Oct 2020 18:08:06

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:31:55

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:17:26
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
User entered '14 Jan 2021' reason for change: Data Entry Error	Shetel Anassi (b) (4)	25 Mar 2021 18:50:13
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 16:35:22
Query 'Data is required. Please complete.' answered with 'data correct' (Site from System).	Shetel Anassi (b) (4)	06 Nov 2020 20:20:49
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:13:56
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	06 Nov 2020 20:13:56
	(b) (4)	
User entered '25 Sep 2020'	Shetel Anassi (b) (4)	06 Nov 2020 20:08:39
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:31:55

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.	(b) (4)	02 Apr 2021 17:17:26
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
User entered 'Other (OTHER)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	25 Mar 2021 18:50:13
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 16:35:24
Query 'Data is required. Please complete.' answered with 'data correct' (Site from System).	Shetel Anassi (b) (4)	06 Nov 2020 20:20:46
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:13:56
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	06 Nov 2020 20:13:56
	(b) (4)	
User entered 'Pregnancy (PREGNANCY)'	Shetel Anassi (b) (4)	06 Nov 2020 20:08:39
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:31:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:17:26
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
User entered 'Subject ublinded for EUA vaccine'	Shetel Anassi (b) (4)	25 Mar 2021 18:50:13
reason for change: Data Entry Error	(b) (4)	
User entered empty.	Shetel Anassi (b) (4)	06 Nov 2020 20:08:39
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:31:55

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:17:26
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
User entered empty.	Shetel Anassi (b) (4)	06 Nov 2020 20:08:39
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:31:55

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:17:26
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
User entered empty.	Shetel Anassi (b) (4)	06 Nov 2020 20:08:39
	(b) (4)	



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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:31:55

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:17:26
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
User entered empty.	(b) (4)	
	Shetel Anassi (b) (4)	06 Nov 2020 20:08:39
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:31:55

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:56
DataPoint Verified.		02 Apr 2021 17:17:26
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:02
	(b) (4)	
User entered empty.	Shetel Anassi (b) (4)	06 Nov 2020 20:08:39
	(b) (4)	