

US3112128 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:12:21

All time stamps listed in this document are displayed in GMT

US3112128

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

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[Participant ID](#)

US3112128

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

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US3112128

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:46:26

Generated On: 09 Jun 2021 15:12:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3112128

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:46:26

Generated On: 09 Jun 2021 15:12:21

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	30
Age Units	YEARS
Age (Derived)	30
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	False
Black	False
Asian	True
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:46:26

Generated On: 09 Jun 2021 15:12:21

Date of Informed Consent ( <i>dd MMM yyyy</i> )	6 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input 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

US3112128

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:46:26

Generated On: 09 Jun 2021 15:12:21

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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) 19 Feb 2021 16:46:26

Generated On: 09 Jun 2021 15:12:21

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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) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

Condition	TYPE 1 DIABETES
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

Condition	BILATERAL ALLERGIC CONJUNCTIVITIS
Start date (dd MMM yyyy)	02 AUG 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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

Condition	SULFA ALLERGY
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

Condition	VANCOMYCIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1993
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	JAN 1993
Stop Year (derived)	1993



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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

Condition	PILONIDAL CYST
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

Condition	PILONIDAL CYST
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

Condition	ADENOIDECTOMY
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

Condition	NASAL SINUS SURGERY
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

Condition	LACRIMAL DUCT DILATION
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 12 Mar 2021 16:34:16

Generated On: 09 Jun 2021 15:12:21

Condition	BILATERAL ANKLE FLEA BITES
Start date (dd MMM yyyy)	UN JUL 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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:46:26

Generated On: 09 Jun 2021 15:12:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	06 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	10:00 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 10:00
Height ( <i>xxx.x</i> )	66 in
Weight ( <i>xxx.x</i> )	116.6 lb
BMI ( <i>xxx.x</i> )	18.85908 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:46:26

Generated On: 09 Jun 2021 15:12:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 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) 19 Feb 2021 16:46:26

Generated On: 09 Jun 2021 15:12:21

Date of assessment (dd MMM yyyy) 06 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) 19 Feb 2021 16:46:26

Generated On: 09 Jun 2021 15:12:21

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 06 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:46:26

Generated On: 09 Jun 2021 15:12:21

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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) 19 Feb 2021 16:46:26

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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)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 143165

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

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) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

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)	06 AUG 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 10:00
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	111 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	92 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	11:58 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 11:58
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	116 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

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) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

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) 6 AUG 2020

What was the treatment time? (00:00-23:59) 11:27 (24 HR)

Treatment Date and Time (derived) 6 AUG 2020 11:27

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) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 AUG 2020
Collection time (00:00-23:59)	10:58 (24 HR)
Collection date and time (derived)	06 AUG 2020 10:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

Collection date (dd MMM yyyy)			06 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:49	06 AUG 2020 10:49
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

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: 09 Jun 2021 15:12:21

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 12:00

PC Open Date & Time

06 AUG 2020 11:47

PC Close Date & Time

06 AUG 2020 14:17



US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	06 AUG 2020 18:01
PC Open Date & Time	06 AUG 2020 15:12
PC Close Date & Time	07 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:12:21

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 18:08

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:12:21

**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

97.9 °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

08 AUG 2020 21:46

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:12:21

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.1 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

09 AUG 2020 18:09

---

PC Open Date & Time

09 AUG 2020 12:00

---

PC Close Date & Time

10 AUG 2020 11:59

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US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 18:55

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 15:59

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

12 AUG 2020 18:40

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 8

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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 13 AUG 2020 17:27

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59



US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 17:22

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 12:01

PC Open Date & Time

06 AUG 2020 11:47

PC Close Date & Time

06 AUG 2020 14:17

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

**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

06 AUG 2020 18:02

PC Open Date & Time

06 AUG 2020 15:12

PC Close Date & Time

07 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:12:21

**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

07 AUG 2020 18:09

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:12:21

**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

08 AUG 2020 21:47

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:12:21

**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

09 AUG 2020 18:10

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:12:21

**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

10 AUG 2020 18:55

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:12:21

**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

11 AUG 2020 16:00

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59



US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:12:21

**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

12 AUG 2020 18:41

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

**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 ☐

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 12:01
PC Open Date & Time	06 AUG 2020 11:47
PC Close Date & Time	06 AUG 2020 14:17

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

**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 ☐

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 18:02
PC Open Date & Time	06 AUG 2020 15:12
PC Close Date & Time	07 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:12:21

**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 ☒

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EAB) (1725)

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:12:21

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 18:09
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:12:21

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 ☒



US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:12:21

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 21:47
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:12:21

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 ☒

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:12:21

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 18:10
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:12:21

**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 ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:12:21

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 18:56
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:12:21

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

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EAB) (1725)

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:12:21

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 16:00
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:12:21

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 ☐



US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:12:21

		Yes <input type="checkbox"/>
PC Time stamp	12 AUG 2020 18:41	
PC Open Date & Time	12 AUG 2020 12:00	
PC Close Date & Time	13 AUG 2020 11:59	

US3112128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:12:21

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 AUG 2020 17:27
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3112128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 15:12:21

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 AUG 2020 17:22
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3112128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:37:35

Generated On: 09 Jun 2021 15:12:21

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

UNABLE TO REACH PATIENT  
DUE TO SITE SCHEDULING  
ERROR.

If Contact Not Made, please provide Comments

US3112128

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:37:35

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:37:35

Generated On: 09 Jun 2021 15:12:21

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

UNABLE TO REACH PATIENT  
DUE TO SITE SCHEDULING  
ERROR.

If Contact Not Made, please provide Comments

US3112128

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:37:35

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:37:35

Generated On: 09 Jun 2021 15:12:21

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

UNABLE TO REACH PATIENT  
DUE TO SITE SCHEDULING  
ERROR.

If Contact Not Made, please provide Comments



US3112128

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:37:35

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

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 VISIT2

US3112128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

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

US3112128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

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

US3112128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

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.*

US3112128

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

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

US3112128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

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? \_\_\_\_\_

US3112128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

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

Collection date ( <i>dd MMM yyyy</i> )	<hr/>
--	-------

Collection time ( <i>00:00-23:59</i> )	<hr/>
--	-------

Collection date and time (derived)	<hr/>
------------------------------------	-------



US3112128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:12:21

Collection date ( <i>dd MMM yyyy</i> )			
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3112128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:45:29

Generated On: 09 Jun 2021 15:12:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

ONE CONTACT MADE WITHIN  
VISIT WINDOW AFTER PATIENT  
EXITED CONVALESCENT  
PHASE.

*If Contact Not Made, please provide Comments*

US3112128

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:37:35

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:45:29

Generated On: 09 Jun 2021 15:12:21

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 OCT 2020

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

Comments TWO TIMES CONTACT  
ATTEMPTS MADE;  
02OCT2020 AT 0815  
05OCT2020 AT 1247  
NO CONTACT MADE,  
CERTIFIED LETTER SENT

*If Contact Not Made, please provide Comments*

US3112128

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:45:29

Generated On: 09 Jun 2021 15:12:21

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

NO CONTACT ATTEMPT MADE,  
CERTIFIED LETTER  
PREVIOUSLY SENT

*If Contact Not Made, please provide Comments*

US3112128

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

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

US3112128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

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

US3112128

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

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.*

US3112128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

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

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

US3112128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:50:29

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

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"/>

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

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"/>



**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

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 <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"/>

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 106
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"/>



**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2020 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 DEC 2020 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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05 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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09 DEC 2020 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 131

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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19 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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23 DEC 2020 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 145

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2020 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 152

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JAN 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JAN 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 08:35:11

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 09:36:35

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 17:39:23

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 FEB 2021 20:30:19

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 12:00:26

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59



US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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27 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2021 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 215

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2021 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 222

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 MAR 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2021 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 236

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2021 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 243

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 APR 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 APR 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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17 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2021 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 264

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 APR 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 271

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59



US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 JUN 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 JUN 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUL 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 341

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2021 23:59



US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	_____
<a href="#">Patient Cloud Open Date &amp; Time</a>	31 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 AUG 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59



US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 SEP 2021 23:59



US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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



US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 460

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 NOV 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 NOV 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 DEC 2021 23:59



US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 DEC 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 DEC 2021 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59



US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 JAN 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59



US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

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02 FEB 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 FEB 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3112128**

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

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**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

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02 MAR 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 MAR 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59



US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 APR 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 APR 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59



US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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30 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUN 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3112128**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59



US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 712

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 SEP 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 SEP 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2022 23:59



US3112128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C)

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 OCT 2022 23:59

**US3112128**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 15:12:21**

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

US3112128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:45:29

Generated On: 09 Jun 2021 15:12:21

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

MISSED D85 SAFETY  
PHONECALL DUE TO  
SCHEDULING ERROR AS NO PT.  
VISIT FOR D57 COMPLETED. PT  
WAS IN CONVALESCENT  
PHASE DURING D57 WINDOW.

US3112128

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:45:29

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 DEC 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112128

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 JAN 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3112128

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 FEB 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112128

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3112128**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:12:21**

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 \_\_\_\_\_

US3112128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3112128

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

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.*

**US3112128**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:12:21**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<input type="text"/>
Collection time ( <i>00:00-23:59</i> )	<input type="text"/>
Collection date and time (derived)	<input type="text"/>

**US3112128**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Date of Contact	18 SEP 2020
Time of Contact	09:00
Date and Time of Contact (derived)	18 SEP 2020 09:00
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	101 F
-------------	-------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.9 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	19 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 SEP 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>



US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 SEP 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Date of Visit	18 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	18 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

---

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

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US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Date of Contact	26 OCT 2020
Time of Contact	10:00
Date and Time of Contact (derived)	26 OCT 2020 10:00
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	25 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	26 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.5 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	27 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.9 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.9 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Date of Visit	26 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	26 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3112128

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	20 SEP 2020
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 OCT 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3112128

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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	SICKD1



US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	18 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	09:18 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 09:18
Height ( <i>xxx.x</i> )	ND - Not Done
Weight ( <i>xxx.x</i> )	ND - Not Done
Temperature ( <i>xxx.x</i> )	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	90 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	101 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112128

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3112128

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 SEP 2020

US3112128

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 10:10
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	106 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112128

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3112128

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 OCT 2020

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

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 SICKD28



US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

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) \_\_\_\_\_

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

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.*

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	22 JAN 2021
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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	UNBLND_DECIDE
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US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Date of updated informed consent ( <i>dd MMM yyyy</i> )	22 JAN 2021
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 ( <i>dd MMM yyyy</i> )	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input 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 checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	22 JAN 2021
Time of assessment (00:00-23:59)	14:02 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 14:02
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	118 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 15:35
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	110 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG



US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

22 JAN 2021

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

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US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	22 JAN 2021
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)	

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 15:04 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 15:04

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

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

14:25 (24 HR)

Collection date and time (derived)

22 JAN 2021 14:25

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	22 JAN 2021
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Collection time (00:00 - 23:59)	14:12
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Collection Date and Time (derived)	22 JAN 2021 14:12
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US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:01:53

Generated On: 09 Jun 2021 15:12:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112128

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:01:53

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1



US3112128

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	22 FEB 2021
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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	OLD29
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US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 21:02:22

Generated On: 09 Jun 2021 15:12:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	22 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	13:13 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 13:13
Temperature ( <i>xxx.x</i> )	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	104 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

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)	22 FEB 2021
Time of assessment (00:00-23:59)	13:13 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 13:13
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	104 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3112128

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

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.*

US3112128

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

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) \_\_\_\_\_

US3112128

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

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

SUBJECT CAME IN FOR OPEN LABEL 1 MONTH FOLLOW UP BECAUSE SHE PREVIOUSLY RECEIVED 1ST DOSE THEN CAME INTO O-L DECISION VISIT APPROVED BY STUDY AND GOT 2ND DOSE.

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? \_\_\_\_\_

US3112128

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 21:02:22

Generated On: 09 Jun 2021 15:12:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	22 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	13:16 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	22 FEB 2021 13:16
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US3112128

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:01:53

Generated On: 09 Jun 2021 15:12:21

Was Contact Attempted? Yes ☐  
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

NOT NEEDED AS PER TABLE 22  
OF PROTOCOL.

If Contact Not Made, please provide Comments

US3112128

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:01:53

Generated On: 09 Jun 2021 15:12:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112128

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

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 OLD57

US3112128

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

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) \_\_\_\_\_

US3112128

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

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.*

US3112128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 22:51:34

Generated On: 09 Jun 2021 15:12:21

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3112128

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:20:53

Generated On: 09 Jun 2021 15:12:21

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

AEID	
Adverse event	FEVER
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3112128

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

AEID	
Adverse event	INTERMITTENT RIGHT LOWER QUADRANT PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3112128

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

---

SEEN IN ER. OBTAINED  
MEDICAL RECORDS GIVEN  
ROCEPHIN, DOXY, CEFTIN PER  
MEDICAL RECORDS BUT NO  
DOSAGES OR DURATION  
REPORTED. PER PT. ALSO  
GIVEN MS . CT SCAN (-)  
WORKIP (-). NO OBVIOUS  
ETIOLOGY.

---

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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US3112128

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

AEID	
Adverse event	CONCUSSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 Apr 2021 21:01:50

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3112128

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

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PT. EXPERIENCED HEAD  
INJURY WEEKS PRIOR TO  
ADMISSION TO HOSPITAL. PI  
HAS UPDATED SERIOUSNESS  
AS THIS WAS NOT THE MAIN  
COMPLAINT FOR HOSPITAL  
ADMISSION.

PI UPDATED STATUS FROM SAE  
TO AE PER REVIEW OF  
MEDICAL RECORDS.

---

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

AEID	USA-US062-2020-MRNA-1273-P30 1000011
Adverse event	DIABETIC KETOACIDOSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	24 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
PATIENT PRESENTED FOR DIABETIC KETOACIDOSIS.	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3112128

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

AEID

Adverse event

UTI LEUKOCYTOSIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

AEID

Adverse event

VAGINAL CANDIDIASIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

23 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

AEID	
Adverse event	UTI
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 02 Apr 2021 21:01:50

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 02 Apr 2021 21:01:50

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AEID

Adverse event

VIRAL SYNDROME

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

25 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 21:01:50

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Name of Medication TRESIBA

Prophylaxis Yes ☐  
No ☒

Indication TYPE 1 DIABETES

Dose per administration 32

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNITS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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 UNK 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 21:01:50

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Name of Medication HUMALOG

Prophylaxis Yes ☐  
No ☒

Indication TYPE 1 DIABETES

Dose per administration 12-30

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNITS

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 EVERY MEAL

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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 UNK 2002	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication DUREZOL OPHTHALMIC DROP

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL CONJUNCTIVITIS  
ALLERGIC

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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)	UN AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	07 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication CYCLOPENTOLATE  
HYDROCHLORIDE

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL CONJUNCTIVITIS  
ALLERGIES

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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)	UN AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	07 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 21:01:50

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Name of Medication ERRIN

Prophylaxis Yes ☐  
No ☒

Indication BIRTH CONTROL

Dose per administration 0.35

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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 MAY 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication RLQ PAIN

Dose per administration UNK

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication ROCEPHIN IV

Prophylaxis Yes ☐  
No ☒

Indication UTI

Dose per administration UNK

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☒  
No ☐

Indication PREVENTATIVE FOR  
POTENTIAL PID (PER MEDICAL  
RECORDS)

Dose per administration UNK

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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)	12 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication CEFTIN

Prophylaxis Yes ☐  
No ☒

Indication UTI

Dose per administration UNK

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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)	12 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐  
No ☒

Indication UTI LEUKOCYTOSIS

Dose per administration 2

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☒  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify Q24H

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	24 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication FLUCONAZOLE

Prophylaxis Yes ☐  
No ☒

Indication VAGINAL CANDIDIASIS

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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)	23 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR DISORDER

Dose per administration 150

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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 UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR DISORDER

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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)	23 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication LITHIUM

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR DISORDER

Dose per administration 300

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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 UNK 2018	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication LANTUS

Prophylaxis Yes ☐  
No ☒

Indication DIABETIC KETOACIDOSIS

Dose per administration 32

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNITS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication KEFLEX

Prophylaxis Yes ☐  
No ☒

Indication UTI LEUKOCYTOSIS

Dose per administration 250

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☒  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication FLU PROPHYLAXIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	Intramuscular	<input checked="" 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)		16 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)		16 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication VIRAL SYNDROME

Dose per administration 800

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 21:01:50

Generated On: 09 Jun 2021 15:12:21

	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)		25 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) 25 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"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:12:21

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 09 Jun 2021 15:12:21

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

Date of dosing discontinuation (dd MMM yyyy) 18 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

PT. UNABLE TO CONTINUE DUE TO RLQ (AE#2) CONCERNS RELATED TO ONGOING AE, PER PI

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:12:21

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

SAEID	USA-US062-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

SAEID	USA-US062-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/DEC/2020 11:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

SAEID	USA-US062-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/JAN/2021 11:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 21:01:52

Generated On: 09 Jun 2021 15:12:21

SAEID	USA-US062-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/JAN/2021 11:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3112128 (Prod: Medical Center For Clinical Research - M3 Wake Research)



**US3112128**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:12:21**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 18:22:17
User entered 'US3112128'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 17:39:15

US3112128

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:30:12
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:12

US3112128

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:30:12
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 17:39:16

US3112128

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:30:12
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:12

**US3112128**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:12:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'SCRN'	System	06 Aug 2020 18:32:12

US3112128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:16
User entered (b) (6) 1990'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 17:39:17

US3112128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:16
User entered '30'	Matthew Musikanth (b) (4)	07 Aug 2020 01:16:23

**US3112128**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:12:21**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'YEARS'	System	07 Aug 2020 01:16:23



US3112128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '30'	System	06 Aug 2020 18:32:21

US3112128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:21

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:16
User entered 'Female (F)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:16:23

US3112128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:16
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:16:23

US3112128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:21

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:16
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:16:23

US3112128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:21

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:16
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:16:23

US3112128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:21

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:16
User entered 'I'	Matthew Musikanth (b) (4)	07 Aug 2020 01:16:23

US3112128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:16
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:16:23

US3112128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:16
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:16:23



US3112128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:16
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:16:23

US3112128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:21

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:16
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:16:23

US3112128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:21

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:16
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:16:23

**US3112128**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:12:21**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:16
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:16:23

US3112128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:21

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:53
User entered '6 Aug 2020'	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:21

US3112128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:21

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Aug 2020'	System	06 Aug 2020 18:32:21

**US3112128**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:12:21**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2020'	System	06 Aug 2020 18:32:21

US3112128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:53
User entered 'Amendment 1 (1)'	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:21



US3112128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:21

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:21

US3112128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:21

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:53
User entered empty.	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:21

US3112128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:53
User entered empty.	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:21

US3112128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:21

US3112128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:53
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 17:39:16

**US3112128**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:12:21**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'I'	System	06 Aug 2020 18:32:25

US3112128

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:12:21

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:33:00
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:25

US3112128

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:12:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:04:57
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User closed query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 12:18:21
Query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	22 Sep 2020 18:53:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	22 Sep 2020 18:53:08
User opened query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:56:04
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:17:48



US3112128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:48:09
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Type 1 diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 18:55:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:55:39
Data point term sent to Coder	System	22 Sep 2020 18:54:52
User entered 'Type 1 Diabetes'	Matthew Musikanth (b) (4)	22 Sep 2020 18:54:22

US3112128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:48:09
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 2002'	(b) (4) Matthew Musikanth (b) (4)	22 Sep 2020 18:54:22

US3112128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:48:09
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	22 Sep 2020 18:54:22

**US3112128**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:48:09
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	22 Sep 2020 18:54:22

US3112128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:21

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:48:09
Signature has been broken.	Matthew Musikanth	11 Mar 2021 19:31:40
User signature succeeded.	(b) (4) Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered empty.	(b) (4) Matthew Musikanth	22 Sep 2020 18:54:22
	(b) (4)	

US3112128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
Signature has been broken.	(b) (4)	11 Mar 2021 19:48:44
DataPoint Verified.	Matthew Musikanth (b) (4)	11 Mar 2021 19:48:09
User signature succeeded.	(b) (4), (b) (6)	11 Mar 2021 19:48:09
User entered '0'	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
	(b) (4)	22 Sep 2020 18:54:22
	Matthew Musikanth	
	(b) (4)	

**US3112128**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2002'	System	22 Sep 2020 18:54:22

**US3112128**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2002'	System	22 Sep 2020 18:54:22



US3112128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	22 Sep 2020 18:54:22

**US3112128**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	22 Sep 2020 18:54:22

US3112128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:12:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:50:50
User coded data point as SOC: Eye disorders, HLGT: Ocular infections, irritations and inflammations, HLT: Conjunctival infections, irritations and inflammations, PT: Conjunctivitis allergic, LLT: Allergic conjunctivitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 19:47:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 19:47:00
Data point term sent to Coder	System	11 Mar 2021 19:46:14
Coding entries removed.	Matthew Musikanth	11 Mar 2021 19:45:27
Signature has been broken.	(b) (4) Matthew Musikanth	11 Mar 2021 19:45:27
User entered 'BILATERAL Allergic CONJUNCTIVITIS' reason for change: Data Entry Error	(b) (4) Matthew Musikanth	11 Mar 2021 19:45:27
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:46:26
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Eye and eyelid infections, PT: Conjunctivitis, LLT: Conjunctivitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 16:13:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 16:13:55
Data point term sent to Coder	System	18 Feb 2021 16:12:51
User entered 'Bilateral Conjunctivitis'	Matthew Musikanth (b) (4)	18 Feb 2021 16:11:55

US3112128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:50:50
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '02 Aug 2020'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:11:55

US3112128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:50:50
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:11:55

**US3112128**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:12:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:50:50
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	18 Feb 2021 16:11:55

**US3112128**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:12:21**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:50:50
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered empty.	Matthew Musikanth (b) (4)	18 Feb 2021 16:11:55

**US3112128**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:50:50
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	Matthew Musikanth (b) (4)	18 Feb 2021 16:11:55



US3112128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:12:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Aug 2020'	System	18 Feb 2021 16:11:55

**US3112128**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2020'	System	18 Feb 2021 16:11:55

**US3112128**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	18 Feb 2021 16:11:55

US3112128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:12:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	18 Feb 2021 16:11:55

US3112128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:12:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:35
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 16:13:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 16:13:55
Data point term sent to Coder	System	18 Feb 2021 16:12:54
User entered 'tonsillitis'	Matthew Musikanth (b) (4)	18 Feb 2021 16:12:22

US3112128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:35
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 1993'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:12:22

US3112128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:12:21

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:35
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:12:22

**US3112128**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:12:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:35
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	18 Feb 2021 16:12:22



**US3112128**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:12:21**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:35
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered empty.	Matthew Musikanth (b) (4)	18 Feb 2021 16:12:22

US3112128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:12:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:35
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:12:22

US3112128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:12:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 1993'	System	18 Feb 2021 16:12:22

**US3112128**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '1993'	System	18 Feb 2021 16:12:22

US3112128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:12:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	18 Feb 2021 16:12:22

US3112128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:12:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	18 Feb 2021 16:12:22

US3112128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:12:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:48
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 16:13:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 16:13:53
Data point term sent to Coder	System	18 Feb 2021 16:12:54
User entered 'Gerd'	Matthew Musikanth (b) (4)	18 Feb 2021 16:12:35

US3112128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:51:48
Signature has been broken.	Matthew Musikanth (b) (4)	11 Mar 2021 19:49:03
User entered 'UN UNK 1997' reason for change:	Matthew Musikanth	11 Mar 2021 19:49:03
Data Entry Error	(b) (4)	
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 1993'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:12:35



**US3112128**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:12:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:48
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:12:35

US3112128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:12:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:48
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 16:12:50
User entered 'Yes (Y)' reason for change: Data Entry Error	System	18 Feb 2021 16:12:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth	18 Feb 2021 16:12:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 16:12:35
User entered empty.	System	18 Feb 2021 16:12:35
User entered empty.	Matthew Musikanth	18 Feb 2021 16:12:35
User entered empty.	(b) (4)	

**US3112128**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:12:21**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:48
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered empty.	Matthew Musikanth (b) (4)	18 Feb 2021 16:12:35

US3112128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:12:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:48
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:12:35

US3112128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:12:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 1997'	System	11 Mar 2021 19:49:03
User entered 'Jan 1993'	System	18 Feb 2021 16:12:35

**US3112128**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '1997'	System	11 Mar 2021 19:49:03
User entered '1993'	System	18 Feb 2021 16:12:35

US3112128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:12:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	18 Feb 2021 16:12:35

US3112128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:12:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	18 Feb 2021 16:12:35



US3112128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:12:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:57
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Feb 2021 16:36:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 16:36:53
Data point term sent to Coder	System	18 Feb 2021 16:36:20
User entered 'Ovarian Cyst'	Matthew Musikanth (b) (4)	18 Feb 2021 16:35:47

US3112128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:57
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 2006'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:35:47

US3112128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:12:21

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:57
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:35:47

**US3112128**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:12:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:57
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Feb 2021 16:35:47

**US3112128**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:12:21**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:57
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 2006'	Matthew Musikanth (b) (4)	18 Feb 2021 16:35:47

US3112128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:12:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:51:57
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:35:47

US3112128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:12:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2006'	System	18 Feb 2021 16:35:47

US3112128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:12:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2006'	System	18 Feb 2021 16:35:47



**US3112128**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2006'	System	18 Feb 2021 16:35:47

**US3112128**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2006'	System	18 Feb 2021 16:35:47

US3112128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:12:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Feb 2021 16:36:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 16:36:53
Data point term sent to Coder	System	18 Feb 2021 16:36:19
User entered 'Bipolar Disorder'	Matthew Musikanth (b) (4)	18 Feb 2021 16:36:07

US3112128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 1999'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:36:07

US3112128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:12:21

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:36:07

**US3112128**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:12:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	18 Feb 2021 16:36:07

**US3112128**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:12:21**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered empty.	Matthew Musikanth (b) (4)	18 Feb 2021 16:36:07

US3112128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:12:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:36:07



US3112128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:12:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 1999'	System	18 Feb 2021 16:36:07

**US3112128**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '1999'	System	18 Feb 2021 16:36:07

US3112128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:12:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	18 Feb 2021 16:36:07

**US3112128**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	18 Feb 2021 16:36:07

US3112128

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:12:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 16:48:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 16:48:53
Data point term sent to Coder	System	18 Feb 2021 16:48:29
User entered 'Sulfa Allergy'	Matthew Musikanth (b) (4)	18 Feb 2021 16:47:38

US3112128

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 2010'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:47:38

US3112128

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:47:38

**US3112128**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:12:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	18 Feb 2021 16:47:38



**US3112128**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:12:21**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered empty.	Matthew Musikanth (b) (4)	18 Feb 2021 16:47:38

US3112128

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:12:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:47:38

US3112128

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:12:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2010'	System	18 Feb 2021 16:47:38

**US3112128**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2010'	System	18 Feb 2021 16:47:38

**US3112128**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	18 Feb 2021 16:47:38

**US3112128**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	18 Feb 2021 16:47:38

US3112128

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:12:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 16:48:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 16:48:55
Data point term sent to Coder	System	18 Feb 2021 16:48:29
User entered 'Vancomycin Allergy'	Matthew Musikanth (b) (4)	18 Feb 2021 16:47:57

**US3112128**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:12:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 2010'	Matthew Musikanth (b) (4)	18 Feb 2021 16:47:57



US3112128

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:47:57

**US3112128**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:12:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	18 Feb 2021 16:47:57

US3112128

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:12:21

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:47:57

**US3112128**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	Matthew Musikanth (b) (4)	18 Feb 2021 16:47:57

US3112128

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:12:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2010'	System	18 Feb 2021 16:47:57

**US3112128**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2010'	System	18 Feb 2021 16:47:57

**US3112128**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	18 Feb 2021 16:47:57

**US3112128**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	18 Feb 2021 16:47:57



US3112128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:12:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
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.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 16:49:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 16:49:52
Data point term sent to Coder	System	18 Feb 2021 16:49:31
User entered 'tonsillectomy'	Matthew Musikanth (b) (4)	18 Feb 2021 16:48:41

US3112128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 1993'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:48:41

US3112128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:12:21

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:48:41

US3112128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:12:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 16:58:52
User entered 'No (N)' reason for change: Data Entry Error	System	18 Feb 2021 16:58:52
User opened query 'Data is required. Please complete.' (Site from System).	Matthew Musikanth	18 Feb 2021 16:58:52
User entered empty.	(b) (4)	
	System	18 Feb 2021 16:48:41
	Matthew Musikanth	18 Feb 2021 16:48:41
	(b) (4)	

**US3112128**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:12:21**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 1993' reason for change:	(b) (4)	
Data Entry Error	Matthew Musikanth	18 Feb 2021 16:58:52
User entered empty.	(b) (4)	
	Matthew Musikanth	18 Feb 2021 16:48:41
	(b) (4)	

**US3112128**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:48:41

US3112128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:12:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 1993'	System	18 Feb 2021 16:48:41

**US3112128**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '1993'	System	18 Feb 2021 16:48:41



US3112128

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:12:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 1993'	System	18 Feb 2021 16:58:52
User entered empty.	System	18 Feb 2021 16:48:41

**US3112128**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '1993'	System	18 Feb 2021 16:58:52
User entered empty.	System	18 Feb 2021 16:48:41

US3112128

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:12:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Skin structures and soft tissue infections, PT: Pilonidal cyst, LLT: Pilonidal cyst - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 17:06:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 17:06:54
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Skin structures and soft tissue infections, PT: Pilonidal cyst, LLT: Pilonidal cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 16:51:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 16:51:54
Data point term sent to Coder	System	18 Feb 2021 16:50:31
User entered 'Pilonidal Cyst'	Matthew Musikanth (b) (4)	18 Feb 2021 16:49:35

US3112128

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 2013'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:49:35

**US3112128**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:12:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:49:35

**US3112128**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:12:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Feb 2021 16:49:35

US3112128

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:12:21

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 2013'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:49:35

**US3112128**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:49:35



US3112128

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:12:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2013'	System	18 Feb 2021 16:49:35

US3112128

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:12:21

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2013'	System	18 Feb 2021 16:49:35

US3112128

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:12:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2013'	System	18 Feb 2021 16:49:35

**US3112128**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2013'	System	18 Feb 2021 16:49:35

US3112128

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:12:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Skin structures and soft tissue infections, PT: Pilonidal cyst, LLT: Pilonidal cyst - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 16:51:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 16:51:53
Data point term sent to Coder	System	18 Feb 2021 16:50:31
User entered 'Pilonidal Cyst'	Matthew Musikanth (b) (4)	18 Feb 2021 16:49:53

US3112128

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:12:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 2016'	Matthew Musikanth (b) (4)	18 Feb 2021 16:49:53

**US3112128**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:12:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	Matthew Musikanth (b) (4)	18 Feb 2021 16:49:53

**US3112128**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:12:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Feb 2021 16:49:53



**US3112128**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:12:21**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 2016'	Matthew Musikanth (b) (4)	18 Feb 2021 16:49:53

**US3112128**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:49:53

US3112128

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:12:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2016'	System	18 Feb 2021 16:49:53

**US3112128**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2016'	System	18 Feb 2021 16:49:53

US3112128

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:12:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2016'	System	18 Feb 2021 16:49:53

**US3112128**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2016'	System	18 Feb 2021 16:49:53

US3112128

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:12:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:57:02
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 09:57:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Adenoidectomy, LLT: Adenoidectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:41:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:41:53
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	05 Mar 2021 16:41:18
Data point term sent to Coder	System	05 Mar 2021 16:41:15
Coding entries removed.	Matthew Musikanth (b) (4)	05 Mar 2021 16:40:40
Signature has been broken.	Matthew Musikanth (b) (4)	05 Mar 2021 16:40:40
User entered 'Adenoidectomy' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:40:40
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:26:19
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:46:26

US3112128

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:12:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 16:53:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 16:53:54
Data point term sent to Coder	System	18 Feb 2021 16:53:33
User entered 'Sinus Surgery'	Matthew Musikanth (b) (4)	18 Feb 2021 16:53:05



US3112128

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 2013'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:53:05

US3112128

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	Matthew Musikanth (b) (4)	18 Feb 2021 16:53:05

**US3112128**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:12:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Feb 2021 16:53:05

US3112128

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:12:21

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 2013'	Matthew Musikanth (b) (4)	18 Feb 2021 16:53:05

US3112128

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:12:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:53:05

US3112128

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:12:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2013'	System	18 Feb 2021 16:53:05

**US3112128**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2013'	System	18 Feb 2021 16:53:05

US3112128

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:12:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2013'	System	18 Feb 2021 16:53:05



**US3112128**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2013'	System	18 Feb 2021 16:53:05

US3112128

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:12:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:57:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:21:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:21:49
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 09:58:06
Data point term sent to Coder	System	05 Mar 2021 16:43:18
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	05 Mar 2021 16:43:12
Coding entries removed.	Matthew Musikanth (b) (4)	05 Mar 2021 16:42:26
Signature has been broken.	Matthew Musikanth (b) (4)	05 Mar 2021 16:42:26
User entered 'NASAL SINUS SURGERY' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:42:26
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:26:36
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:46:26

US3112128

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:12:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 16:53:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 16:53:54
Data point term sent to Coder	System	18 Feb 2021 16:53:34
User entered 'Sinus Surgery'	Matthew Musikanth (b) (4)	18 Feb 2021 16:53:24

**US3112128**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:12:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 2016'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:53:24

US3112128

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:53:24

**US3112128**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:12:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Feb 2021 16:53:24

**US3112128**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:12:21**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered 'un UNK 2016'	Matthew Musikanth (b) (4)	18 Feb 2021 16:53:24

US3112128

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:12:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	18 Feb 2021 16:53:24



**US3112128**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2016'	System	18 Feb 2021 16:53:24

US3112128

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:12:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2016'	System	18 Feb 2021 16:53:24

US3112128

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:12:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2016'	System	18 Feb 2021 16:53:24

**US3112128**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2016'	System	18 Feb 2021 16:53:24

US3112128

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:12:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lacrimal apparatus therapeutic procedures, PT: Lacrimal duct procedure, LLT: Lacrimal duct procedure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 11:32:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 11:32:16
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:02
Data point term sent to Coder	System	11 Mar 2021 19:39:06
User entered 'LACRIMAL DUCT DILATION'	Matthew Musikanth (b) (4)	11 Mar 2021 19:38:48

US3112128

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:57:02
User entered 'un UNK 2002'	Matthew Musikanth (b) (4)	11 Mar 2021 19:38:48

**US3112128**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:12:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:57:02
User entered '0'	Matthew Musikanth (b) (4)	11 Mar 2021 19:38:48

US3112128

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:12:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:57:02
User entered 'No (N)'	Matthew Musikanth (b) (4)	11 Mar 2021 19:38:48



US3112128

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:12:21

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:57:02
User entered 'un UNK 2002'	Matthew Musikanth (b) (4)	11 Mar 2021 19:38:48

**US3112128**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:57:02
User entered '0'	Matthew Musikanth (b) (4)	11 Mar 2021 19:38:48

US3112128

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:12:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2002'	System	11 Mar 2021 19:38:48

**US3112128**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2002'	System	11 Mar 2021 19:38:48

US3112128

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:12:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jan 2002'	System	11 Mar 2021 19:38:48

**US3112128**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2002'	System	11 Mar 2021 19:38:48

US3112128

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:12:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Arthropod bite, LLT: Flea bite - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Mar 2021 13:08:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Mar 2021 13:08:36
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:11
Data point term sent to Coder	System	11 Mar 2021 19:40:07
User entered 'Bilateral Ankle Flea Bites'	Matthew Musikanth (b) (4)	11 Mar 2021 19:39:36

US3112128

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:12:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:56:11
User entered 'un Jul 2020'	Matthew Musikanth (b) (4)	11 Mar 2021 19:39:36



US3112128

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:56:11
User entered '0'	Matthew Musikanth (b) (4)	11 Mar 2021 19:39:36

**US3112128**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:12:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:56:11
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	11 Mar 2021 19:39:36

US3112128

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:12:21

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:56:11
User entered empty.	Matthew Musikanth (b) (4)	11 Mar 2021 19:39:36

**US3112128**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Mar 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:56:11
User entered '0'	Matthew Musikanth (b) (4)	11 Mar 2021 19:39:36

US3112128

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:12:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'Jul 2020'	System	11 Mar 2021 19:39:36

**US3112128**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:12:21**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '2020'	System	11 Mar 2021 19:39:36

**US3112128**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	11 Mar 2021 19:39:36

**US3112128**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:12:21**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	11 Mar 2021 19:39:36



US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:46:43
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:18:40

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:46:43
User entered '06 Aug 2020'	Matthew Musikanth (b) (4)	07 Aug 2020 01:18:40

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:46:43
User entered '10:00'	Matthew Musikanth (b) (4)	07 Aug 2020 01:18:40

**US3112128**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered '06 Aug 2020 10:00'	System	07 Aug 2020 01:18:40

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:46:43
User entered '66' in	Matthew Musikanth	07 Aug 2020 01:18:40
DataPoint set to visible.	(b) (4) System	06 Aug 2020 18:32:25

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:46:43
User entered '116.6' lb	Matthew Musikanth	07 Aug 2020 01:18:40
DataPoint set to visible.	(b) (4) System	06 Aug 2020 18:32:25

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
Amendment Manager: User entered '18.85908'	System	16 Sep 2020 23:45:51
User entered '18.9'	System	07 Aug 2020 01:18:40
DataPoint set to visible.	System	06 Aug 2020 18:32:25

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'kg/m2'	System	07 Aug 2020 01:18:40
DataPoint set to visible.	System	06 Aug 2020 18:32:25



US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:46:43
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 14:36:54
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'Updated ' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 04:43:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 04:43:29
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 19:33:49
User entered '97.6' F	Matthew Musikanth (b) (4)	07 Aug 2020 01:18:40

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:46:43
User entered empty; reason for change Data Entry Error	Karen Mylerberg (b) (4)	05 Sep 2020 04:43:29
User entered 'Oral (Oral)'	(b) (4) Matthew Musikanth (b) (4)	07 Aug 2020 01:18:40

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:46:43
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:18:40

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:46:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4)	05 Sep 2020 04:43:29
User entered '111'	(b) (4) Matthew Musikanth (b) (4)	07 Aug 2020 01:18:40

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'bpm'	System	07 Aug 2020 01:18:40

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:46:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4)	05 Sep 2020 04:43:29
User entered '16'	Matthew Musikanth (b) (4)	07 Aug 2020 01:18:40

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'breaths/min'	System	07 Aug 2020 01:18:40

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:46:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4)	05 Sep 2020 04:43:29
User entered '92'	(b) (4) Matthew Musikanth (b) (4)	07 Aug 2020 01:18:40



US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'mmHg'	System	07 Aug 2020 01:18:40

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:46:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 04:43:29
User entered '55'	Matthew Musikanth (b) (4)	07 Aug 2020 01:18:40

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered 'mmHg'	System	07 Aug 2020 01:18:40

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55

US3112128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55

US3112128

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:49:32
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:18:49

US3112128

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:49:32
User entered '06 Aug 2020'	Matthew Musikanth (b) (4)	07 Aug 2020 01:18:49

US3112128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:12:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:49:44
User entered '06 Aug 2020'	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:23



US3112128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:12:21

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:49:44
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:23

US3112128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:12:21

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:49:44
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:23

US3112128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:12:21

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:49:44
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:23

US3112128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:12:21

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:49:44
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:23

**US3112128**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:12:21**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:49:44
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:23

US3112128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:12:21

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:49:44
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:23

**US3112128**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:12:21**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:49:44
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:23

US3112128

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:50:40
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:37



US3112128

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:50:40
User entered '06 Aug 2020'	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:37

US3112128

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:50:40
User entered 'Urine (URINE)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:37

US3112128

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:50:40
User entered 'Negative (NEGATIVE)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:37

US3112128

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
Query 'Per CDM: Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' canceled (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 00:19:57
User opened query 'Per CDM: Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:05:37
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:32:10
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User closed query 'Per CDM: Per page 24 of CCGs, please select Yes or No to indicate if FSH sample collected. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:18:35
Query 'Per CDM: Per page 24 of CCGs, please select Yes or No to indicate if FSH sample collected. Thank you.' answered with 'resolved' (Site from DM).	Matthew Musikanth (b) (4)	22 Sep 2020 18:51:58
DataPoint Un-verified.	Matthew Musikanth (b) (4)	22 Sep 2020 18:51:53
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	22 Sep 2020 18:51:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 18:50:40
User opened query 'Per CDM: Per page 24 of CCGs, please select Yes or No to indicate if FSH sample collected. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 05:46:41
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:37

US3112128

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:50:40
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:37

US3112128

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:50:40
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:19:37

**US3112128**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:12:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User entered empty.	System	07 Aug 2020 01:19:37

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10



US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

**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)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

**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)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

[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)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

**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)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

**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)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

[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)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10



US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

**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)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

**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)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

**Resides in Nursing Home or Assisted Living Facility**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

**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)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

**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)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10



US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

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)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered 'I'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
User entered '0'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:25:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:52:10
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:10

US3112128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:23:29
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:26

US3112128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:23:29
User entered '06 Aug 2020'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:26

US3112128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:23:29
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:26

**US3112128**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:12:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'VISIT1'	System	07 Aug 2020 01:20:26



US3112128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:21

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:24:51
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 17:54:37

US3112128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:21

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:24:51
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:35:52
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:35:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 17:54:37
User entered '143165' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 17:54:37

US3112128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:21

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:24:51
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 17:54:37

US3112128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:21

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)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:24:51
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:35

US3112128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:21

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)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:24:51
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:35

US3112128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:21

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:24:51
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:35

US3112128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:21

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:24:51
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:35

US3112128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:24:51
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:20:35



US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 04:43:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 04:43:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 04:43:52
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 01:21:40
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered '06 Aug 2020'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered '10:00'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40



US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered '06 Aug 2020 10:00'	System	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered '97.6' F	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered '111'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'bpm'	System	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered '16'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'breaths/min'	System	07 Aug 2020 01:21:40



US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered '92'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'mmHg'	System	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:21:42
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	29 Sep 2020 17:26:16
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 18:29:24
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:45:51
User entered '55'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'mmHg'	System	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 04:43:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 04:43:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 04:43:52
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 01:21:40
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered '06 Aug 2020'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 17:16:02
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 01:21:40
User entered '11:58'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered '06 Aug 2020 11:58'	System	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered '98.1' F	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered '116'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'bpm'	System	07 Aug 2020 01:21:40



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered '18'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'breaths/min'	System	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered '100'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'mmHg'	System	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:24
User entered '60'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'mmHg'	System	07 Aug 2020 01:21:40

US3112128

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:31:14
User closed query 'Per source, PE was performed on 06Aug2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	12 Oct 2020 21:31:10
Query 'Per source, PE was performed on 06Aug2020. Please confirm and update as necessary.' answered with 'yes, however this PE is captured within the screening EDC folder as screening and randomization visit were combined and this is aligned with the EDC guidelines' (Site from CRA).	Nicolle Mendez (b) (4) (b) (4)	24 Sep 2020 00:21:12
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	24 Sep 2020 00:20:04
User opened query 'Per source, PE was performed on 06Aug2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 18:55:13
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	07 Aug 2020 01:21:48
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:48

US3112128

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:31:14
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	24 Sep 2020 00:20:04
User entered '06 Aug 2020'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:48



US3112128

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:38:12
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User closed query 'Per CDM: Per CCGs pages 16-17 when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test should be removed from this page. Please update accordingly.' (Site from DM). Query 'Per CDM: Per CCGs pages 16-17 when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test should be removed from this page. Please update accordingly.' answered with 'updatd' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:27:09
User entered 'No (N)' reason for change: Per Query Resolution	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 16:18:28
User opened query 'Per CDM: Per CCGs pages 16-17 when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test should be removed from this page. Please update accordingly.' (Site from DM).	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 16:18:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 13:45:11
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test data should be removed from this page. Please update accordingly.' (Site from DM). Query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test data should be removed from this page. Please update accordingly.' answered with 'updated per query' (Site from DM).	Natalie Moy (b) (4) (b) (4), (b) (6)	08 Oct 2020 15:41:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 12:18:46
	Matthew Musikanth (b) (4)	22 Sep 2020 18:52:34
	Matthew Musikanth (b) (4)	22 Sep 2020 18:52:26

US3112128

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and V1D1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test data should be removed from this page. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:09:40
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:59

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:38:12
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered empty; reason for change Per Query Resolution	(b) (4)	
	Natalie Moy (b) (4)	09 Nov 2020 16:18:12
User entered '6 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Natalie Moy (b) (4)	08 Oct 2020 15:41:31
User entered empty; reason for change Data Entry Error	(b) (4)	
	Matthew Musikanth	22 Sep 2020 18:52:26
	(b) (4)	
User entered '06 Aug 2020'	Matthew Musikanth	07 Aug 2020 01:21:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:38:12
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered empty; reason for change Per Query Resolution	(b) (4)	
	Natalie Moy (b) (4)	09 Nov 2020 16:18:12
User entered 'Urine (URINE)' reason for change: Data Entry Error	(b) (4)	
	Natalie Moy (b) (4)	08 Oct 2020 15:41:31
User entered empty; reason for change Data Entry Error	(b) (4)	
	Matthew Musikanth	22 Sep 2020 18:52:26
	(b) (4)	
User entered 'Urine (URINE)'	Matthew Musikanth	07 Aug 2020 01:21:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:38:12
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered empty; reason for change Per Query Resolution	(b) (4)	
	Natalie Moy (b) (4)	09 Nov 2020 16:18:12
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4)	
	Natalie Moy (b) (4)	08 Oct 2020 15:41:31
User entered empty; reason for change Data Entry Error	(b) (4)	
	Matthew Musikanth	22 Sep 2020 18:52:26
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Matthew Musikanth	07 Aug 2020 01:21:59
	(b) (4)	

US3112128

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:38:12
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User closed query 'Per CDM: Screening and V1D1 have occurred on a same day. Please consider to mark response for Was FSH sample collected? as No' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:03:20
Query 'Per CDM: Screening and V1D1 have occurred on a same day. Please consider to mark response for Was FSH sample collected? as No' answered with 'updated' (Site from DM).	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 15:41:38
User entered 'No (N)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 15:40:50
User opened query 'Per CDM: Screening and V1D1 have occurred on a same day. Please consider to mark response for Was FSH sample collected? as No' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:19:12
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:59

US3112128

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:38:12
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:27:12
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' answered with 'updated' (Site from DM).	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 16:18:34
User entered empty; reason for change Per Query Resolution	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 16:18:12
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:43:53
User entered '6 Aug 2020' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 15:41:31
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:21:59

US3112128

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:38:12
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered empty; reason for change Per Query Resolution	(b) (4)	
	Natalie Moy (b) (4)	09 Nov 2020 16:18:12
User entered '11:09' reason for change: Data Entry Error	(b) (4)	
	Natalie Moy (b) (4)	08 Oct 2020 15:41:31
User entered empty.	Matthew Musikanth	07 Aug 2020 01:21:59
	(b) (4)	



US3112128

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered empty.	System	09 Nov 2020 16:18:12
User entered '6 Aug 2020 11:09'	System	08 Oct 2020 15:41:31
User entered empty.	System	07 Aug 2020 01:21:59

US3112128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:26:06
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:42

US3112128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:26:06
User entered empty.	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:42

US3112128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

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)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:26:06
User entered empty.	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:42

US3112128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 18:32:42

US3112128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:26:06
User entered '6 Aug 2020'	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:42

US3112128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:26:06
User entered '11:27'	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:42

US3112128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered '6 Aug 2020 11:27'	System	06 Aug 2020 18:32:42



US3112128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:26:06
User entered 'Left Arm (LEFT ARM)'	Matthew Musikanth (b) (4)	06 Aug 2020 18:32:42

US3112128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 18:26:06
User entered 'ONCE'	System	06 Aug 2020 18:32:42

US3112128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 18:32:42

US3112128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:57:48
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:22:16

US3112128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:57:48
User entered '06 Aug 2020'	Matthew Musikanth (b) (4)	07 Aug 2020 01:22:16

US3112128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:57:48
User entered '10:58'	Matthew Musikanth (b) (4)	07 Aug 2020 01:22:16

**US3112128**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:12:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered '06 Aug 2020 10:58'	System	07 Aug 2020 01:22:16

US3112128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:12:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:58:07
User entered '06 Aug 2020'	Matthew Musikanth (b) (4)	07 Aug 2020 01:22:31



US3112128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:12:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:22:31

US3112128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:12:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:58:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:22:31

US3112128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:12:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:58:07
User entered '10:49'	Matthew Musikanth (b) (4)	07 Aug 2020 01:22:31

US3112128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:12:21

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered '06 Aug 2020 10:49'	System	07 Aug 2020 01:22:31

US3112128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:12:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:22:31

US3112128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:12:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:58:07
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 21:49:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 21:49:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 21:49:42
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 01:22:31
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:22:31

US3112128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:12:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:58:07
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 01:22:31

US3112128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:12:21

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered empty.	System	07 Aug 2020 01:22:31



US3112128

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:58:17
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:22:35

US3112128

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'I'	System	07 Aug 2020 01:22:35

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:00:09', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '4a3d0fd9-591a-479b-8dd5-703615bef011'	System	06 Aug 2020 19:00:26
User entered 'Yes (Y)'	System	06 Aug 2020 19:00:26

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:00:15', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '4a3d0fd9-591a-479b-8dd5-703615bef011'	System	06 Aug 2020 19:00:26
User entered '98.1'	System	06 Aug 2020 19:00:26

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:00:20', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '4a3d0fd9-591a-479b-8dd5-703615bef011'	System	06 Aug 2020 19:00:26
User entered 'No (N)'	System	06 Aug 2020 19:00:26

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:00:24', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '4a3d0fd9-591a-479b-8dd5-703615bef011'	System	06 Aug 2020 19:00:26
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 19:00:26

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '06 Aug 2020 11:47'	System	06 Aug 2020 18:32:42



US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '06 Aug 2020 14:17'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:01:23', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '33cba5d0-7a26-4842-9c49-bd4664f8b8b4'	System	07 Aug 2020 01:01:43
User entered 'Yes (Y)'	System	07 Aug 2020 01:01:43

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:01:34', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '33cba5d0-7a26-4842-9c49-bd4664f8b8b4' User entered '98.1'	System	07 Aug 2020 01:01:43
	System	07 Aug 2020 01:01:43

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:01:37', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '33cba5d0-7a26-4842-9c49-bd4664f8b8b4'	System	07 Aug 2020 01:01:43
User entered 'No (N)'	System	07 Aug 2020 01:01:43

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:01:40', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '33cba5d0-7a26-4842-9c49-bd4664f8b8b4'	System	07 Aug 2020 01:01:43
User entered '06 Aug 2020 18:01'	System	07 Aug 2020 01:01:43

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '06 Aug 2020 15:12'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 18:32:42



US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 2'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:12:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:07:25', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'ded2ca4e-3190-487e-959f-9373e63dc788'	System	08 Aug 2020 01:08:25
User entered 'Yes (Y)'	System	08 Aug 2020 01:08:25

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:12:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:08:15', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'ded2ca4e-3190-487e-959f-9373e63dc788'	System	08 Aug 2020 01:08:25
User entered '97.8'	System	08 Aug 2020 01:08:25

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:12:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:08:18', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'ded2ca4e-3190-487e-959f-9373e63dc788'	System	08 Aug 2020 01:08:25
User entered 'No (N)'	System	08 Aug 2020 01:08:25

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:08:22', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'ded2ca4e-3190-487e-959f-9373e63dc788'	System	08 Aug 2020 01:08:25
User entered '07 Aug 2020 18:08'	System	08 Aug 2020 01:08:25

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 3'	System	06 Aug 2020 18:32:42



US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:12:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:45:44', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b4254b21-170f-4175-8885-8eb1882b4ed6'	System	09 Aug 2020 04:46:54
User entered 'Yes (Y)'	System	09 Aug 2020 04:46:54

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:12:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:46:47', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b4254b21-170f-4175-8885-8eb1882b4ed6'	System	09 Aug 2020 04:46:54
User entered '97.9'	System	09 Aug 2020 04:46:54

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:12:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:46:50', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b4254b21-170f-4175-8885-8eb1882b4ed6'	System	09 Aug 2020 04:46:54
User entered 'No (N)'	System	09 Aug 2020 04:46:54

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:46:53', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b4254b21-170f-4175-8885-8eb1882b4ed6'	System	09 Aug 2020 04:46:54
User entered '08 Aug 2020 21:46'	System	09 Aug 2020 04:46:54

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 4'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:12:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:08:59', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b2119466-881b-49ec-859b-3d10eeffbac1'	System	10 Aug 2020 01:09:47
User entered 'Yes (Y)'	System	10 Aug 2020 01:09:47



US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:12:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:09:40', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b2119466-881b-49ec-859b-3d10eeffbac1'	System	10 Aug 2020 01:09:47
User entered '98.1'	System	10 Aug 2020 01:09:47

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:12:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:09:42', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b2119466-881b-49ec-859b-3d10eeffbac1'	System	10 Aug 2020 01:09:47
User entered 'No (N)'	System	10 Aug 2020 01:09:47

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:09:45', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b2119466-881b-49ec-859b-3d10eeffbac1'	System	10 Aug 2020 01:09:47
User entered '09 Aug 2020 18:09'	System	10 Aug 2020 01:09:47

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 5'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:12:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:55:28', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '0641d17f-9154-484e-b2e6-064867bf2dd0'	System	11 Aug 2020 01:55:39
User entered 'Yes (Y)'	System	11 Aug 2020 01:55:39

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:12:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:55:31', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '0641d17f-9154-484e-b2e6-064867bf2dd0'	System	11 Aug 2020 01:55:39
User entered '98.2'	System	11 Aug 2020 01:55:39



US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:12:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:55:34', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '0641d17f-9154-484e-b2e6-064867bf2dd0'	System	11 Aug 2020 01:55:39
User entered 'No (N)'	System	11 Aug 2020 01:55:39

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:55:37', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '0641d17f-9154-484e-b2e6-064867bf2dd0'	System	11 Aug 2020 01:55:39
User entered '10 Aug 2020 18:55'	System	11 Aug 2020 01:55:39

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 6'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:12:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T15:59:46', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'f8d15668-dcbe-40d6-9733-9f0e1edc3c26'	System	11 Aug 2020 22:59:59
User entered 'Yes (Y)'	System	11 Aug 2020 22:59:59

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:12:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T15:59:50', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'f8d15668-dcbe-40d6-9733-9f0e1edc3c26'	System	11 Aug 2020 22:59:59
User entered '98.3'	System	11 Aug 2020 22:59:59

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:12:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T15:59:52', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'f8d15668-dcbe-40d6-9733-9f0e1edc3c26'	System	11 Aug 2020 22:59:59
User entered 'No (N)'	System	11 Aug 2020 22:59:59



US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T15:59:56', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'f8d15668-dcbe-40d6-9733-9f0e1edc3c26'	System	11 Aug 2020 22:59:59
User entered '11 Aug 2020 15:59'	System	11 Aug 2020 22:59:59

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 7'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:12:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:40:32', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '2cf14ca9-3880-4eb5-9fd7-63a612ca982d'	System	13 Aug 2020 01:40:52
User entered 'Yes (Y)'	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:12:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:40:36', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '2cf14ca9-3880-4eb5-9fd7-63a612ca982d' User entered '97.4'	System	13 Aug 2020 01:40:52
	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:12:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:40:41', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '2cf14ca9-3880-4eb5-9fd7-63a612ca982d'	System	13 Aug 2020 01:40:52
User entered 'Yes (Y)'	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:12:21

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	24 Oct 2020 12:53:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:40:47', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '2cf14ca9-3880-4eb5-9fd7-63a612ca982d'	Matthew Musikanth (b) (4)	20 Oct 2020 20:39:41
User entered '1'	System	13 Aug 2020 01:40:52



US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:12:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:40:47', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '2cf14ca9-3880-4eb5-9fd7-63a612ca982d' User entered '0'	System	13 Aug 2020 01:40:52
	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:40:49', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '2cf14ca9-3880-4eb5-9fd7-63a612ca982d'	System	13 Aug 2020 01:40:52
User entered '12 Aug 2020 18:40'	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	13 Aug 2020 01:40:52
User entered 'Day 8'	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:12:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-13T17:26:10', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '67c8b01a-63b3-4e44-869d-6db608236b93'	System	14 Aug 2020 00:27:19
User entered 'Yes (Y)'	System	14 Aug 2020 00:27:19

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:12:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-13T17:27:08', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '67c8b01a-63b3-4e44-869d-6db608236b93'	System	14 Aug 2020 00:27:19
User entered '98.0'	System	14 Aug 2020 00:27:19

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:12:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-13T17:27:10', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '67c8b01a-63b3-4e44-869d-6db608236b93'	System	14 Aug 2020 00:27:19
User entered 'Yes (Y)'	System	14 Aug 2020 00:27:19



US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:12:21

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	24 Oct 2020 12:54:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Matthew Musikanth	20 Oct 2020 20:39:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-13T17:27:13', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '67c8b01a-63b3-4e44-869d-6db608236b93'	(b) (4)	
User entered '1'	System	14 Aug 2020 00:27:19
	System	14 Aug 2020 00:27:19
	System	14 Aug 2020 00:27:19

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:12:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-13T17:27:13', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '67c8b01a-63b3-4e44-869d-6db608236b93'	System	14 Aug 2020 00:27:19
User entered '0'	System	14 Aug 2020 00:27:19

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-13T17:27:16', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '67c8b01a-63b3-4e44-869d-6db608236b93'	System	14 Aug 2020 00:27:19
User entered '13 Aug 2020 17:27'	System	14 Aug 2020 00:27:19

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	13 Aug 2020 01:40:52
User entered 'Day 9'	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:12:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-14T17:22:18', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '61fb488f-dfe8-4700-b464-9a0db6e0ee0e'	System	15 Aug 2020 00:22:30
User entered 'Yes (Y)'	System	15 Aug 2020 00:22:30

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:12:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-14T17:22:21', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '61fb488f-dfe8-4700-b464-9a0db6e0ee0e'	System	15 Aug 2020 00:22:30
User entered '98.5'	System	15 Aug 2020 00:22:30



US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:12:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-14T17:22:23', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '61fb488f-dfe8-4700-b464-9a0db6e0ee0e'	System	15 Aug 2020 00:22:30
User entered 'No (N)'	System	15 Aug 2020 00:22:30

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-14T17:22:26', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '61fb488f-dfe8-4700-b464-9a0db6e0ee0e'	System	15 Aug 2020 00:22:30
User entered '14 Aug 2020 17:22'	System	15 Aug 2020 00:22:30

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:00:38', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '79402c50-d481-4056-9b80-6aca6b0267c8'	System	06 Aug 2020 19:01:11
User entered 'None (1)'	System	06 Aug 2020 19:01:11

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:00:46', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '79402c50-d481-4056-9b80-6aca6b0267c8'	System	06 Aug 2020 19:01:11
User entered 'No (N)'	System	06 Aug 2020 19:01:11

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:00:53', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '79402c50-d481-4056-9b80-6aca6b0267c8'	System	06 Aug 2020 19:01:11
User entered 'No (N)'	System	06 Aug 2020 19:01:11



US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:01:05', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '79402c50-d481-4056-9b80-6aca6b0267c8'	System	06 Aug 2020 19:01:11
User entered 'None (1)'	System	06 Aug 2020 19:01:11

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:01:08', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '79402c50-d481-4056-9b80-6aca6b0267c8'	System	06 Aug 2020 19:01:11
User entered '06 Aug 2020 12:01'	System	06 Aug 2020 19:01:11

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '06 Aug 2020 11:47'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '06 Aug 2020 14:17'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:01:52', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '08e27929-a633-4591-905e-519eab36da7a'	System	07 Aug 2020 01:02:16
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 01:02:16

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:01:55', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '08e27929-a633-4591-905e-519eab36da7a'	System	07 Aug 2020 01:02:16
User entered 'No (N)'	System	07 Aug 2020 01:02:16

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:02:01', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '08e27929-a633-4591-905e-519eab36da7a'	System	07 Aug 2020 01:02:16
User entered 'No (N)'	System	07 Aug 2020 01:02:16



US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:02:11', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '08e27929-a633-4591-905e-519eab36da7a'	System	07 Aug 2020 01:02:16
User entered 'None (1)'	System	07 Aug 2020 01:02:16

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:02:14', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '08e27929-a633-4591-905e-519eab36da7a'	System	07 Aug 2020 01:02:16
User entered '06 Aug 2020 18:02'	System	07 Aug 2020 01:02:16

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '06 Aug 2020 15:12'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 2'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:12:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:08:40', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '30d8997f-fcc5-4e58-add9-6d0ee77b64b6'	System	08 Aug 2020 01:09:09
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 01:09:09

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:12:21

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:08:52', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '30d8997f-fcc5-4e58-add9-6d0ee77b64b6'	System	08 Aug 2020 01:09:09
User entered 'No (N)'	System	08 Aug 2020 01:09:09

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:12:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:08:56', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '30d8997f-fcc5-4e58-add9-6d0ee77b64b6'	System	08 Aug 2020 01:09:09
User entered 'No (N)'	System	08 Aug 2020 01:09:09



US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:12:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:09:04', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '30d8997f-fcc5-4e58-add9-6d0ee77b64b6'	System	08 Aug 2020 01:09:09
User entered 'None (1)'	System	08 Aug 2020 01:09:09

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:09:07', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '30d8997f-fcc5-4e58-add9-6d0ee77b64b6'	System	08 Aug 2020 01:09:09
User entered '07 Aug 2020 18:09'	System	08 Aug 2020 01:09:09

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 3'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:12:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:47:02', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '37a525ce-79e4-40b5-a122-7d2543091b05'	System	09 Aug 2020 04:47:27
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 04:47:27

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:12:21

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:47:05', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '37a525ce-79e4-40b5-a122-7d2543091b05'	System	09 Aug 2020 04:47:27
User entered 'No (N)'	System	09 Aug 2020 04:47:27

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:12:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:47:07', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '37a525ce-79e4-40b5-a122-7d2543091b05'	System	09 Aug 2020 04:47:27
User entered 'No (N)'	System	09 Aug 2020 04:47:27



US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:12:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:47:19', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '37a525ce-79e4-40b5-a122-7d2543091b05'	System	09 Aug 2020 04:47:27
User entered 'None (1)'	System	09 Aug 2020 04:47:27

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:47:23', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '37a525ce-79e4-40b5-a122-7d2543091b05'	System	09 Aug 2020 04:47:27
User entered '08 Aug 2020 21:47'	System	09 Aug 2020 04:47:27

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 4'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:12:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:09:50', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '0ff7f38b-6289-459d-9cdd-164af4ac8968'	System	10 Aug 2020 01:10:06
User entered 'None (1)'	System	10 Aug 2020 01:10:06

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:12:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:09:52', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '0ff7f38b-6289-459d-9cdd-164af4ac8968'	System	10 Aug 2020 01:10:06
User entered 'No (N)'	System	10 Aug 2020 01:10:06

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:12:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:09:55', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '0ff7f38b-6289-459d-9cdd-164af4ac8968'	System	10 Aug 2020 01:10:06
User entered 'No (N)'	System	10 Aug 2020 01:10:06



US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:12:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:09:58', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '0ff7f38b-6289-459d-9cdd-164af4ac8968'	System	10 Aug 2020 01:10:06
User entered 'None (1)'	System	10 Aug 2020 01:10:06

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:10:00', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '0ff7f38b-6289-459d-9cdd-164af4ac8968'	System	10 Aug 2020 01:10:06
User entered '09 Aug 2020 18:10'	System	10 Aug 2020 01:10:06

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 5'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:12:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:55:42', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'ba97372b-bf0b-4866-bf2a-a62a831dab63'	System	11 Aug 2020 01:55:59
User entered 'None (1)'	System	11 Aug 2020 01:55:59

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:12:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:55:45', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'ba97372b-bf0b-4866-bf2a-a62a831dab63'	System	11 Aug 2020 01:55:59
User entered 'No (N)'	System	11 Aug 2020 01:55:59

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:12:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:55:48', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'ba97372b-bf0b-4866-bf2a-a62a831dab63'	System	11 Aug 2020 01:55:59
User entered 'No (N)'	System	11 Aug 2020 01:55:59



US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:12:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:55:51', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'ba97372b-bf0b-4866-bf2a-a62a831dab63'	System	11 Aug 2020 01:55:59
User entered 'None (1)'	System	11 Aug 2020 01:55:59

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:55:54', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'ba97372b-bf0b-4866-bf2a-a62a831dab63'	System	11 Aug 2020 01:55:59
User entered '10 Aug 2020 18:55'	System	11 Aug 2020 01:55:59

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 6'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:12:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T16:00:00', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '4eb9838a-c55c-4d2b-9d24-941dbadc5f88'	System	11 Aug 2020 23:00:14
User entered 'None (1)'	System	11 Aug 2020 23:00:14

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:12:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T16:00:03', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '4eb9838a-c55c-4d2b-9d24-941dbadc5f88'	System	11 Aug 2020 23:00:14
User entered 'No (N)'	System	11 Aug 2020 23:00:14

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:12:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T16:00:05', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '4eb9838a-c55c-4d2b-9d24-941dbadc5f88'	System	11 Aug 2020 23:00:14
User entered 'No (N)'	System	11 Aug 2020 23:00:14



US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:12:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T16:00:08', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '4eb9838a-c55c-4d2b-9d24-941dbadc5f88'	System	11 Aug 2020 23:00:14
User entered 'None (1)'	System	11 Aug 2020 23:00:14

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T16:00:11', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '4eb9838a-c55c-4d2b-9d24-941dbadc5f88'	System	11 Aug 2020 23:00:14
User entered '11 Aug 2020 16:00'	System	11 Aug 2020 23:00:14

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 7'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:12:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:40:54', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'a62e98a1-d003-4756-a399-38fba9e0eccc'	System	13 Aug 2020 01:41:07
User entered 'None (1)'	System	13 Aug 2020 01:41:07

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:12:21

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:40:57', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'a62e98a1-d003-4756-a399-38fba9e0eccc'	System	13 Aug 2020 01:41:07
User entered 'No (N)'	System	13 Aug 2020 01:41:07

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:12:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:41:00', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'a62e98a1-d003-4756-a399-38fba9e0eccc'	System	13 Aug 2020 01:41:07
User entered 'No (N)'	System	13 Aug 2020 01:41:07



US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:12:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:41:02', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'a62e98a1-d003-4756-a399-38fba9e0eccc'	System	13 Aug 2020 01:41:07
User entered 'None (1)'	System	13 Aug 2020 01:41:07

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:12:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:41:04', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'a62e98a1-d003-4756-a399-38fba9e0eccc'	System	13 Aug 2020 01:41:07
User entered '12 Aug 2020 18:41'	System	13 Aug 2020 01:41:07

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:01:20', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'a6317041-060d-4d03-aefb-b4d7148aea53'	System	06 Aug 2020 19:01:53
User entered 'None (0)'	System	06 Aug 2020 19:01:53

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:01:22', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'a6317041-060d-4d03-aefb-b4d7148aea53'	System	06 Aug 2020 19:01:53
User entered 'None (0)'	System	06 Aug 2020 19:01:53

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:01:24', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'a6317041-060d-4d03-aefb-b4d7148aea53'	System	06 Aug 2020 19:01:53
User entered 'None (0)'	System	06 Aug 2020 19:01:53



US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:01:26', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'a6317041-060d-4d03-aefb-b4d7148aea53'	System	06 Aug 2020 19:01:53
User entered 'None (0)'	System	06 Aug 2020 19:01:53

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:01:29', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'a6317041-060d-4d03-aefb-b4d7148aea53'	System	06 Aug 2020 19:01:53
User entered 'None (0)'	System	06 Aug 2020 19:01:53

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:01:31', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'a6317041-060d-4d03-aefb-b4d7148aea53'	System	06 Aug 2020 19:01:53
User entered 'None (0)'	System	06 Aug 2020 19:01:53

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

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)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:01:36', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'a6317041-060d-4d03-aefb-b4d7148aea53'	System	06 Aug 2020 19:01:53
User entered 'No (N)'	System	06 Aug 2020 19:01:53

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T12:01:38', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'a6317041-060d-4d03-aefb-b4d7148aea53'	System	06 Aug 2020 19:01:53
User entered '06 Aug 2020 12:01'	System	06 Aug 2020 19:01:53

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '06 Aug 2020 11:47'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '06 Aug 2020 14:17'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 18:32:42



US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:02:20', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'adec23c3-b622-43ce-abbb-5fdb52d16cb5'	System	07 Aug 2020 01:02:49
User entered 'No interference with activity (1)'	System	07 Aug 2020 01:02:49

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:02:23', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'adec23c3-b622-43ce-abbb-5fdb52d16cb5'	System	07 Aug 2020 01:02:49
User entered 'None (0)'	System	07 Aug 2020 01:02:49

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:02:25', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'adec23c3-b622-43ce-abbb-5fdb52d16cb5'	System	07 Aug 2020 01:02:49
User entered 'None (0)'	System	07 Aug 2020 01:02:49

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:02:28', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'adec23c3-b622-43ce-abbb-5fdb52d16cb5'	System	07 Aug 2020 01:02:49
User entered 'None (0)'	System	07 Aug 2020 01:02:49

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:02:31', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'adec23c3-b622-43ce-abbb-5fdb52d16cb5'	System	07 Aug 2020 01:02:49
User entered 'None (0)'	System	07 Aug 2020 01:02:49

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:02:33', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'adec23c3-b622-43ce-abbb-5fdb52d16cb5'	System	07 Aug 2020 01:02:49
User entered 'None (0)'	System	07 Aug 2020 01:02:49

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

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)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:02:40', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'adec23c3-b622-43ce-abbb-5fdb52d16cb5'	System	07 Aug 2020 01:02:49
User entered 'No (N)'	System	07 Aug 2020 01:02:49

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-06T18:02:47', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'adec23c3-b622-43ce-abbb-5fdb52d16cb5'	System	07 Aug 2020 01:02:49
User entered '06 Aug 2020 18:02'	System	07 Aug 2020 01:02:49



US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '06 Aug 2020 15:12'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 2'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:12:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:09:12', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '821aa011-9f9b-44d5-95c5-5934163f3ff7'	System	08 Aug 2020 01:09:39
User entered 'None (0)'	System	08 Aug 2020 01:09:39

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:12:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:09:16', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '821aa011-9f9b-44d5-95c5-5934163f3ff7'	System	08 Aug 2020 01:09:39
User entered 'None (0)'	System	08 Aug 2020 01:09:39

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:12:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:09:19', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '821aa011-9f9b-44d5-95c5-5934163f3ff7'	System	08 Aug 2020 01:09:39
User entered 'None (0)'	System	08 Aug 2020 01:09:39

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:12:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:09:23', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '821aa011-9f9b-44d5-95c5-5934163f3ff7'	System	08 Aug 2020 01:09:39
User entered 'None (0)'	System	08 Aug 2020 01:09:39

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:12:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:09:26', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '821aa011-9f9b-44d5-95c5-5934163f3ff7'	System	08 Aug 2020 01:09:39
User entered 'None (0)'	System	08 Aug 2020 01:09:39



US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:12:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:09:29', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '821aa011-9f9b-44d5-95c5-5934163f3ff7'	System	08 Aug 2020 01:09:39
User entered 'None (0)'	System	08 Aug 2020 01:09:39

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:12:21

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)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:09:31', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '821aa011-9f9b-44d5-95c5-5934163f3ff7'	System	08 Aug 2020 01:09:39
User entered 'No (N)'	System	08 Aug 2020 01:09:39

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:12:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-07T18:09:33', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '821aa011-9f9b-44d5-95c5-5934163f3ff7'	System	08 Aug 2020 01:09:39
User entered '07 Aug 2020 18:09'	System	08 Aug 2020 01:09:39

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 3'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:12:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:47:29', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b42f7730-e306-459f-88a3-e434ded9a3f9'	System	09 Aug 2020 04:47:55
User entered 'None (0)'	System	09 Aug 2020 04:47:55

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:12:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:47:33', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b42f7730-e306-459f-88a3-e434ded9a3f9'	System	09 Aug 2020 04:47:55
User entered 'None (0)'	System	09 Aug 2020 04:47:55



US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:12:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:47:37', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b42f7730-e306-459f-88a3-e434ded9a3f9'	System	09 Aug 2020 04:47:55
User entered 'None (0)'	System	09 Aug 2020 04:47:55

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:12:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:47:39', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b42f7730-e306-459f-88a3-e434ded9a3f9'	System	09 Aug 2020 04:47:55
User entered 'None (0)'	System	09 Aug 2020 04:47:55

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:12:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:47:42', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b42f7730-e306-459f-88a3-e434ded9a3f9'	System	09 Aug 2020 04:47:55
User entered 'None (0)'	System	09 Aug 2020 04:47:55

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:12:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:47:45', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b42f7730-e306-459f-88a3-e434ded9a3f9'	System	09 Aug 2020 04:47:55
User entered 'None (0)'	System	09 Aug 2020 04:47:55

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:12:21

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)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:47:50', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b42f7730-e306-459f-88a3-e434ded9a3f9'	System	09 Aug 2020 04:47:55
User entered 'No (N)'	System	09 Aug 2020 04:47:55

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:12:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-08T21:47:52', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'b42f7730-e306-459f-88a3-e434ded9a3f9'	System	09 Aug 2020 04:47:55
User entered '08 Aug 2020 21:47'	System	09 Aug 2020 04:47:55

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 18:32:42



US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 4'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:12:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:10:03', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '1a128e30-e465-498a-8529-0bcae748fa87'	System	10 Aug 2020 01:10:23
User entered 'None (0)'	System	10 Aug 2020 01:10:23

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:12:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:10:06', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '1a128e30-e465-498a-8529-0bcae748fa87'	System	10 Aug 2020 01:10:23
User entered 'None (0)'	System	10 Aug 2020 01:10:23

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:12:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:10:08', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '1a128e30-e465-498a-8529-0bcae748fa87'	System	10 Aug 2020 01:10:23
User entered 'None (0)'	System	10 Aug 2020 01:10:23

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:12:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:10:10', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '1a128e30-e465-498a-8529-0bcae748fa87'	System	10 Aug 2020 01:10:23
User entered 'None (0)'	System	10 Aug 2020 01:10:23

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:12:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:10:13', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '1a128e30-e465-498a-8529-0bcae748fa87'	System	10 Aug 2020 01:10:23
User entered 'None (0)'	System	10 Aug 2020 01:10:23

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:12:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:10:15', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '1a128e30-e465-498a-8529-0bcae748fa87'	System	10 Aug 2020 01:10:23
User entered 'None (0)'	System	10 Aug 2020 01:10:23

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:12:21

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)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:10:17', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '1a128e30-e465-498a-8529-0bcae748fa87'	System	10 Aug 2020 01:10:23
User entered 'No (N)'	System	10 Aug 2020 01:10:23



US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:12:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-09T18:10:20', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '1a128e30-e465-498a-8529-0bcae748fa87'	System	10 Aug 2020 01:10:23
User entered '09 Aug 2020 18:10'	System	10 Aug 2020 01:10:23

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 5'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:12:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:56:00', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '60b62bfb-4675-4933-9e35-6fdc40b3dfbd'	System	11 Aug 2020 01:56:19
User entered 'None (0)'	System	11 Aug 2020 01:56:19

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:12:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:56:02', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '60b62bfb-4675-4933-9e35-6fdc40b3dfbd'	System	11 Aug 2020 01:56:19
User entered 'None (0)'	System	11 Aug 2020 01:56:19

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:12:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:56:04', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '60b62bfb-4675-4933-9e35-6fdc40b3dfbd'	System	11 Aug 2020 01:56:19
User entered 'None (0)'	System	11 Aug 2020 01:56:19

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:12:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:56:06', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '60b62bfb-4675-4933-9e35-6fdc40b3dfbd'	System	11 Aug 2020 01:56:19
User entered 'None (0)'	System	11 Aug 2020 01:56:19



US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:12:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:56:08', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '60b62bfb-4675-4933-9e35-6fdc40b3dfbd'	System	11 Aug 2020 01:56:19
User entered 'None (0)'	System	11 Aug 2020 01:56:19

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:12:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:56:11', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '60b62bfb-4675-4933-9e35-6fdc40b3dfbd'	System	11 Aug 2020 01:56:19
User entered 'None (0)'	System	11 Aug 2020 01:56:19

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:12:21

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)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:56:13', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '60b62bfb-4675-4933-9e35-6fdc40b3dfbd'	System	11 Aug 2020 01:56:19
User entered 'No (N)'	System	11 Aug 2020 01:56:19

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:12:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-10T18:56:16', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '60b62bfb-4675-4933-9e35-6fdc40b3dfbd'	System	11 Aug 2020 01:56:19
User entered '10 Aug 2020 18:56'	System	11 Aug 2020 01:56:19

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 6'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:12:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T16:00:23', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'cf67750e-cb7d-46e9-a048-b13f795e8322'	System	11 Aug 2020 23:00:45
User entered 'None (0)'	System	11 Aug 2020 23:00:45



US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:12:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T16:00:26', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'cf67750e-cb7d-46e9-a048-b13f795e8322'	System	11 Aug 2020 23:00:45
User entered 'None (0)'	System	11 Aug 2020 23:00:45

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:12:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T16:00:28', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'cf67750e-cb7d-46e9-a048-b13f795e8322'	System	11 Aug 2020 23:00:45
User entered 'None (0)'	System	11 Aug 2020 23:00:45

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:12:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T16:00:30', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'cf67750e-cb7d-46e9-a048-b13f795e8322'	System	11 Aug 2020 23:00:45
User entered 'None (0)'	System	11 Aug 2020 23:00:45

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:12:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T16:00:32', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'cf67750e-cb7d-46e9-a048-b13f795e8322'	System	11 Aug 2020 23:00:45
User entered 'None (0)'	System	11 Aug 2020 23:00:45

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:12:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T16:00:33', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'cf67750e-cb7d-46e9-a048-b13f795e8322'	System	11 Aug 2020 23:00:45
User entered 'None (0)'	System	11 Aug 2020 23:00:45

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:12:21

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)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T16:00:38', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'cf67750e-cb7d-46e9-a048-b13f795e8322'	System	11 Aug 2020 23:00:45
User entered 'No (N)'	System	11 Aug 2020 23:00:45

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:12:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-11T16:00:40', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'cf67750e-cb7d-46e9-a048-b13f795e8322'	System	11 Aug 2020 23:00:45
User entered '11 Aug 2020 16:00'	System	11 Aug 2020 23:00:45

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 18:32:42



US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 7'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:12:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:41:08', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'c0c20141-544c-4745-9686-f7d126fce08d'	System	13 Aug 2020 01:41:30
User entered 'None (0)'	System	13 Aug 2020 01:41:30

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:12:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:41:10', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'c0c20141-544c-4745-9686-f7d126fce08d'	System	13 Aug 2020 01:41:30
User entered 'None (0)'	System	13 Aug 2020 01:41:30

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:12:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:41:12', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'c0c20141-544c-4745-9686-f7d126fce08d'	System	13 Aug 2020 01:41:30
User entered 'None (0)'	System	13 Aug 2020 01:41:30

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:12:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:41:13', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'c0c20141-544c-4745-9686-f7d126fce08d'	System	13 Aug 2020 01:41:30
User entered 'None (0)'	System	13 Aug 2020 01:41:30

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:12:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:41:16', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'c0c20141-544c-4745-9686-f7d126fce08d'	System	13 Aug 2020 01:41:30
User entered 'None (0)'	System	13 Aug 2020 01:41:30

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:12:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:41:18', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'c0c20141-544c-4745-9686-f7d126fce08d'	System	13 Aug 2020 01:41:30
User entered 'None (0)'	System	13 Aug 2020 01:41:30



US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:12:21

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)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:41:23', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'c0c20141-544c-4745-9686-f7d126fce08d'	System	13 Aug 2020 01:41:30
User entered 'Yes (Y)'	System	13 Aug 2020 01:41:30

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:12:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-12T18:41:27', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'c0c20141-544c-4745-9686-f7d126fce08d'	System	13 Aug 2020 01:41:30
User entered '12 Aug 2020 18:41'	System	13 Aug 2020 01:41:30

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	13 Aug 2020 01:40:52
User entered 'Day 8'	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:12:21

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)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-13T17:27:22', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '3e40e518-6f86-4a67-b02c-d0d239887138'	System	14 Aug 2020 00:27:26
User entered 'No (N)'	System	14 Aug 2020 00:27:26

US3112128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:12:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-13T17:27:24', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '3e40e518-6f86-4a67-b02c-d0d239887138'	System	14 Aug 2020 00:27:26
User entered '13 Aug 2020 17:27'	System	14 Aug 2020 00:27:26

US3112128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 01:40:52



US3112128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
Data entry locked.	System	13 Aug 2020 01:40:52
User entered 'Day 9'	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 15:12:21

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)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-14T17:22:34', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '464e056c-02fe-4f59-bed7-34968fea29b3'	System	15 Aug 2020 00:22:41
User entered 'No (N)'	System	15 Aug 2020 00:22:41

US3112128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 15:12:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2020-08-14T17:22:38', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '464e056c-02fe-4f59-bed7-34968fea29b3'	System	15 Aug 2020 00:22:41
User entered '14 Aug 2020 17:22'	System	15 Aug 2020 00:22:41

US3112128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 15:12:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 01:40:52

US3112128

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 15:12:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:59
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 01:40:52

US3112128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:42:44
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4)	
	System	20 Oct 2020 20:53:41
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	20 Oct 2020 20:53:18
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Oct 2020 20:53:18

US3112128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:42:44
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered empty.	Matthew Musikanth (b) (4)	20 Oct 2020 20:53:18



US3112128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:42:44
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered empty; reason for change Data Entry Error	(b) (4)	
	Matthew Musikanth	20 Oct 2020 20:53:41
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	Matthew Musikanth	20 Oct 2020 20:53:18
	(b) (4)	

US3112128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:42:44
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered 'Unable to reach patient due to site scheduling error.'	(b) (4) Matthew Musikanth (b) (4)	20 Oct 2020 20:53:18

US3112128

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:42:50
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	20 Oct 2020 20:53:27
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Oct 2020 20:53:22

**US3112128**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'I'	System	20 Oct 2020 20:53:27
User entered empty.	System	20 Oct 2020 20:53:22

US3112128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:43:03
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Oct 2020 20:53:49

US3112128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:43:03
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	20 Oct 2020 20:53:49

US3112128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:43:03
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered empty.	Matthew Musikanth (b) (4)	20 Oct 2020 20:53:49

US3112128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:43:03
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered 'Unable to reach patient due to site scheduling error.'	(b) (4) Matthew Musikanth (b) (4)	20 Oct 2020 20:53:49



US3112128

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:43:09
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	20 Oct 2020 20:53:53

**US3112128**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:34
User entered 'I'	System	20 Oct 2020 20:53:53

US3112128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:10
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:43:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Oct 2020 20:56:41

US3112128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:10
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:43:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered empty.	Matthew Musikanth (b) (4)	20 Oct 2020 20:56:41

US3112128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:10
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:43:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered empty.	Matthew Musikanth (b) (4)	20 Oct 2020 20:56:41

US3112128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:10
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:43:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered 'Unable to reach patient due to site scheduling error.'	(b) (4) Matthew Musikanth (b) (4)	20 Oct 2020 20:56:41

US3112128

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:10
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:43:28
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	20 Oct 2020 20:56:47

**US3112128**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:10
User entered 'I'	System	20 Oct 2020 20:56:47



US3112128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:14:15
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	20 Oct 2020 20:56:57

US3112128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:14:15
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	20 Oct 2020 20:56:57

US3112128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:14:15
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	20 Oct 2020 20:56:57

**US3112128**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:12:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered 'VISIT2'	System	20 Oct 2020 20:56:57

US3112128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:13:40
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:09:48

US3112128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered '1'	System	28 Dec 2020 22:09:48

US3112128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:55:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
Signature has been broken.	(b) (4)	
	Matthew Musikanth	26 Feb 2021 00:05:18
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth	26 Feb 2021 00:05:18
	(b) (4)	
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	28 Dec 2020 22:10:10
	(b) (4)	

US3112128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:55:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
Signature has been broken.	(b) (4)	
	Matthew Musikanth	26 Feb 2021 00:05:18
	(b) (4)	
User entered '28 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth	26 Feb 2021 00:05:18
	(b) (4)	
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
	(b) (4)	
User entered empty.	Matthew Musikanth	28 Dec 2020 22:10:10
	(b) (4)	



US3112128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:55:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
Signature has been broken.	(b) (4)	
	Matthew Musikanth	26 Feb 2021 00:05:18
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Matthew Musikanth	26 Feb 2021 00:05:18
User signature succeeded.	(b) (4)	
	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
	(b) (4)	
User entered empty.	Matthew Musikanth	28 Dec 2020 22:10:10
	(b) (4)	

US3112128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:55:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
Signature has been broken.	(b) (4)	
	Matthew Musikanth	26 Feb 2021 00:05:18
	(b) (4)	
User entered 'one contact made within visit window after patient exited convalescent phase.' reason for change: Data Entry Error	Matthew Musikanth	26 Feb 2021 00:05:18
User signature succeeded.	(b) (4)	
	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
	(b) (4)	
User entered empty.	Matthew Musikanth	28 Dec 2020 22:10:10
	(b) (4)	

US3112128

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:55:10
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:37:35
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:10:16

US3112128

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
User entered 'I'	System	28 Dec 2020 22:10:16

US3112128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:56:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
Signature has been broken.	(b) (4)	
	Matthew Musikanth	26 Feb 2021 00:06:52
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth	26 Feb 2021 00:06:52
	(b) (4)	
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	28 Dec 2020 22:10:50
	(b) (4)	

US3112128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:56:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
Signature has been broken.	(b) (4)	
	Matthew Musikanth	26 Feb 2021 00:06:52
	(b) (4)	
User entered '02 Oct 2020' reason for change: Data Entry Error	Matthew Musikanth	26 Feb 2021 00:06:52
	(b) (4)	
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
	(b) (4)	
User entered empty.	Matthew Musikanth	28 Dec 2020 22:10:50
	(b) (4)	

US3112128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:56:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
Signature has been broken.	(b) (4)	
	Matthew Musikanth	26 Feb 2021 00:06:52
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Matthew Musikanth	26 Feb 2021 00:06:52
User signature succeeded.	(b) (4)	
	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
	(b) (4)	
User entered empty.	Matthew Musikanth	28 Dec 2020 22:10:50
	(b) (4)	

US3112128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:56:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
Signature has been broken.	(b) (4) Matthew Musikanth	26 Feb 2021 00:06:52
User entered 'two times contact attempts made; 02OCT2020 at 0815 05OCT2020 at 1247 no contact made, certified letter sent' reason for change: Data Entry Error	(b) (4) Matthew Musikanth	26 Feb 2021 00:06:52
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered empty.	(b) (4) Matthew Musikanth	28 Dec 2020 22:10:50
	(b) (4)	



US3112128

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:56:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:10:55

US3112128

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
User entered 'I'	System	28 Dec 2020 22:10:55

US3112128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:12:13
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	26 Feb 2021 00:09:02
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	26 Feb 2021 00:07:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	28 Dec 2020 22:11:02

US3112128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:12:13
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:11:02

US3112128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:12:13
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
User entered empty; reason for change Data Entry Error	(b) (4)	26 Feb 2021 00:09:02
Signature has been broken.	Matthew Musikanth	26 Feb 2021 00:07:25
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Matthew Musikanth	26 Feb 2021 00:07:25
User signature succeeded.	(b) (4)	
	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
	(b) (4)	
User entered empty.	Matthew Musikanth	28 Dec 2020 22:11:02
	(b) (4)	

US3112128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:12:13
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
Signature has been broken.	(b) (4)	
	Matthew Musikanth	26 Feb 2021 00:07:25
	(b) (4)	
User entered 'no contact attempt made, certified letter previously sent' reason for change: Data Entry Error	Matthew Musikanth	26 Feb 2021 00:07:25
	(b) (4)	
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
	(b) (4)	
User entered empty.	Matthew Musikanth	28 Dec 2020 22:11:02
	(b) (4)	

US3112128

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:12:43
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:11:10

US3112128

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
User entered 'I'	System	28 Dec 2020 22:11:10



**US3112128**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:12:21**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:06:03
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered 'No (N)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:11:31

US3112128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:06:03
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:11:31

US3112128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:06:03
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:11:31

**US3112128**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:12:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
User entered 'VISIT3'	System	28 Dec 2020 22:11:31

US3112128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:06:10
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:50:29
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:11:38

**US3112128**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:48
User entered 'I'	System	28 Dec 2020 22:11:38

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 64'	System	06 Aug 2020 18:32:42

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

Have you been exposed to someone with 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 18:32:42

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 71'	System	06 Aug 2020 18:32:42

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

Have you been exposed to someone with 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 18:32:42

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 78'	System	06 Aug 2020 18:32:42

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

Have you been exposed to someone with 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

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**Folder: Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:12:21**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
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**US3112128**

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 18:32:42

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 92'	System	06 Aug 2020 18:32:42

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

Have you been exposed to someone with 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



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Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 18:32:42

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 99'	System	06 Aug 2020 18:32:42

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

Have you been exposed to someone with 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

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**Folder: Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

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**Folder: Safety Follow Up Diary (1)**

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 18:32:42

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 18:32:42

US3112128

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:12:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered 'Day 106'	System	06 Aug 2020 18:32:42

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

Have you been exposed to someone with 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:21

[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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Please 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)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 18:32:42

**US3112128**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:02:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:55
Data entry locked.	System	06 Aug 2020 18:32:42
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 18:32:42

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:49:55



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-01-23T08:35:00', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'f0c59594-aff4-4232-80dd-df499f2ff325'	System	23 Jan 2021 16:35:13
User entered 'No (N)'	System	23 Jan 2021 16:35:13

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-01-23T08:35:07', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'f0c59594-aff4-4232-80dd-df499f2ff325'	System	23 Jan 2021 16:35:13
User entered 'No (N)'	System	23 Jan 2021 16:35:13

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-01-23T08:35:11', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'f0c59594-aff4-4232-80dd-df499f2ff325'	System	23 Jan 2021 16:35:13
User entered '23 Jan 2021 08:35:11'	System	23 Jan 2021 16:35:13

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-01-30T09:36:26', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '2bc825a4-0c1b-4b51-b57f-520c96f45c1e'	System	30 Jan 2021 17:36:38
User entered 'No (N)'	System	30 Jan 2021 17:36:38

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-01-30T09:36:31', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '2bc825a4-0c1b-4b51-b57f-520c96f45c1e'	System	30 Jan 2021 17:36:38
User entered 'No (N)'	System	30 Jan 2021 17:36:38

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-01-30T09:36:35', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '2bc825a4-0c1b-4b51-b57f-520c96f45c1e'	System	30 Jan 2021 17:36:38
User entered '30 Jan 2021 09:36:35'	System	30 Jan 2021 17:36:38

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-02-09T17:39:16', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '38a8fddf-bcfb-4388-91d4-2faec7440e82'	System	10 Feb 2021 01:39:26
User entered 'No (N)'	System	10 Feb 2021 01:39:26

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-02-09T17:39:20', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '38a8fddf-bcfb-4388-91d4-2faec7440e82'	System	10 Feb 2021 01:39:26
User entered 'No (N)'	System	10 Feb 2021 01:39:26



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-02-09T17:39:23', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '38a8fddf-bcfb-4388-91d4-2faec7440e82'	System	10 Feb 2021 01:39:26
User entered '09 Feb 2021 17:39:23'	System	10 Feb 2021 01:39:26

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-02-16T20:30:12', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '2c23f956-ea3e-41ed-895f-19e5ed1c9c84'	System	17 Feb 2021 04:30:24
User entered 'No (N)'	System	17 Feb 2021 04:30:24

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-02-16T20:30:16', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '2c23f956-ea3e-41ed-895f-19e5ed1c9c84'	System	17 Feb 2021 04:30:24
User entered 'No (N)'	System	17 Feb 2021 04:30:24

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-02-16T20:30:19', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: '2c23f956-ea3e-41ed-895f-19e5ed1c9c84'	System	17 Feb 2021 04:30:24
User entered '16 Feb 2021 20:30:19'	System	17 Feb 2021 04:30:24

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-02-22T12:00:16', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'e3119af7-a348-4c47-94bc-3fab13115d0'	System	22 Feb 2021 20:00:41
User entered 'No (N)'	System	22 Feb 2021 20:00:41

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-02-22T12:00:23', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'e3119af7-a348-4c47-94bc-3fabcd13115d0'	System	22 Feb 2021 20:00:41
User entered 'No (N)'	System	22 Feb 2021 20:00:41

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e76b5dd477d2478)', Time: '2021-02-22T12:00:26', User OID: 'PatientReportedOutcome (US3112128)', ODM File OID: 'e3119af7-a348-4c47-94bc-3fab313115d0'	System	22 Feb 2021 20:00:41
User entered '22 Feb 2021 12:00:26'	System	22 Feb 2021 20:00:41

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:49:55



**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:49:55

**US3112128**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:12:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:55
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:49:55

US3112128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:10
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:07:46
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
User entered 'No (N)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:11:54

US3112128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:10
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:07:46
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:11:54



US3112128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:10
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:07:46
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:11:54

US3112128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:10
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:07:46
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
User entered 'Missed D85 safety phonecall due to scheduling error as no pt. visit for D57 completed. Pt was in convalescent phase during D57 window.'	Matthew Musikanth (b) (4)	05 Mar 2021 16:06:47
reason for change: Data Entry Error		
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:11:54

US3112128

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:13:07
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:29
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:12:00

**US3112128**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:10
User entered 'I'	System	28 Dec 2020 22:12:00

US3112128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:09:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:12:14

US3112128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:09:49
User entered '28 Dec 2020'	Matthew Musikanth (b) (4)	28 Dec 2020 22:12:14

US3112128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:09:49
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:12:14

US3112128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:09:49
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:12:14



US3112128

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:09:52
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:12:20

**US3112128**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User entered 'I'	System	28 Dec 2020 22:12:20

US3112128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:12:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 21:55:46

US3112128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:12:44
User entered '22 Jan 2021'	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 21:55:46

US3112128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:12:44
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 21:55:46

US3112128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:12:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 21:55:46

US3112128

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:12:50
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 21:55:51

**US3112128**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User entered 'I'	System	23 Feb 2021 21:55:51



US3112128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:31:46
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 21:56:20

US3112128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:31:46
User entered '22 Feb 2021'	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 21:56:20

US3112128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:31:46
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 21:56:20

US3112128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:31:46
User entered empty.	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 21:56:20

US3112128

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:31:51
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 21:56:26

**US3112128**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:49
User entered 'I'	System	23 Feb 2021 21:56:26

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:12:21

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:10:12
User entered '18 Sep 2020'	Matthew Musikanth	16 Oct 2020 18:28:21
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:12:21

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:43
	(b) (4)	
	(b) (4)	
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
	(b) (4)	
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 20:20:15
	(b) (4)	
Query 'Please provide source.' answered with 'updated ' (Site from CRA).	Brenda Grande (b) (4)	15 Mar 2021 17:06:47
	(b) (4)	
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 20:11:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:10:12
	(b) (4)	
User entered '09:00'	Matthew Musikanth	16 Oct 2020 18:28:21
	(b) (4)	



US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:12:21

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:43
User entered '18 Sep 2020 09:00'	System	16 Oct 2020 18:28:21

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:12:21

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:10:12
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Matthew Musikanth	16 Oct 2020 18:28:21
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:12:21

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:10:12
User entered 'Yes (Y)'	Matthew Musikanth	16 Oct 2020 18:28:21
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User entered 'Day 1 (Day 1)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '13 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth	11 Mar 2021 21:41:13
	(b) (4)	
User entered '12 Sep 2020'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '0'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered missing code ND - Not Done.	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User entered '%'	System	16 Oct 2020 18:31:42



US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '101' F	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	



US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	



US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:31:42
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	11 Mar 2021 21:41:13
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:00:17
User entered 'Day 6 (Day 6)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:32:51

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '18 Sep 2020'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '0'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '98'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User entered '%'	System	16 Oct 2020 18:32:51

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '97.9' F	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	



US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:32:51
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	11 Mar 2021 21:41:13
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:00:17
User entered 'Day 7 (Day 7)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:33:17



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '19 Sep 2020'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '0'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '99'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User entered '%'	System	16 Oct 2020 18:33:17

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered missing code ND - Not Done.	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:33:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	11 Mar 2021 21:41:13
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:00:17
User entered 'Day 8 (Day 8)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:34:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '20 Sep 2020'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '0'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '98'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User entered '%'	System	16 Oct 2020 18:34:08

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered missing code ND - Not Done.	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	



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Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'None (None)'	Matthew Musikanth	16 Oct 2020 18:34:08
	(b) (4)	

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Form: Symptom Log (6)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User entered 'Day 2 (Day 2)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '14 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth	11 Mar 2021 21:41:13
	(b) (4)	
User entered '13 Sep 2020'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'I'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered missing code ND - Not Done.	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User entered '%'	System	05 Mar 2021 16:00:17



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Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered missing code ND - Not Done.	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Form: Symptom Log (6)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	



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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:12:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User entered 'Day 3 (Day 3)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '15 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth	11 Mar 2021 21:41:13
	(b) (4)	
User entered '14 Sep 2020'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'I'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered missing code ND - Not Done.	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User entered '%'	System	05 Mar 2021 16:00:17

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered missing code ND - Not Done.	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	



US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:12:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User entered 'Day 4 (Day 4)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '16 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth	11 Mar 2021 21:41:13
	(b) (4)	
User entered '15 Sep 2020'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'I'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered missing code ND - Not Done.	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User entered '%'	System	05 Mar 2021 16:00:17

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered missing code ND - Not Done.	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	



US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:12:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User entered 'Day 5 (Day 5)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered '17 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth	11 Mar 2021 21:41:13
	(b) (4)	
User entered '16 Sep 2020'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'I'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	



US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered missing code ND - Not Done.	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User entered '%'	System	05 Mar 2021 16:00:17

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered missing code ND - Not Done.	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	



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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:12:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:30
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:23
User entered 'Not Done (Not Done)'	Matthew Musikanth	05 Mar 2021 16:00:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:15:57
User entered '18 Sep 2020'	Matthew Musikanth	16 Oct 2020 18:36:15
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:15:57
User entered 'Yes (Y)'	Matthew Musikanth	16 Oct 2020 18:36:15
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:15:57
User entered 'No (N)'	Matthew Musikanth	16 Oct 2020 18:36:15
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:15:57
User entered '18 Sep 2020'	Matthew Musikanth	16 Oct 2020 18:36:15
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:15:57
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Matthew Musikanth	16 Oct 2020 18:36:15
	(b) (4)	



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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:15:57
User entered empty.	Matthew Musikanth	16 Oct 2020 18:36:15
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:15:57
User entered 'No (N)'	Matthew Musikanth	16 Oct 2020 18:36:15
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:15:57
User entered empty.	Matthew Musikanth	16 Oct 2020 18:36:15
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:15:57
User entered empty.	Matthew Musikanth	16 Oct 2020 18:36:15
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:16
User entered '0'	System	16 Oct 2020 18:36:15

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:12:21

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:18:05
	(b) (4)	
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User closed query 'Please clarify as COVID assessment dated 26Oct2020 was completed. Please update as necessary.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 22:57:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:57:56
Query 'Please clarify as COVID assessment dated 26Oct2020 was completed. Please update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	11 Mar 2021 22:56:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	11 Mar 2021 22:56:09
User opened query 'Please clarify as COVID assessment dated 26Oct2020 was completed. Please update as necessary.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 20:17:37
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4)	25 Feb 2021 18:55:16
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 17:34:55

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:12:21

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:14:56
User entered '26 Oct 2020'	Matthew Musikanth	26 Oct 2020 18:43:02
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:12:21

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:14:56
User entered '10:00'	Matthew Musikanth	26 Oct 2020 18:43:02
	(b) (4)	



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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:12:21

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:44
User entered '26 Oct 2020 10:00'	System	26 Oct 2020 18:43:02

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:12:21

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:14:56
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Matthew Musikanth	26 Oct 2020 18:43:02
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:12:21

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:14:56
User entered 'Yes (Y)'	Matthew Musikanth	26 Oct 2020 18:43:02
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User entered 'Day 1 (Day 1)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
	(b) (4)	
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:45
	(b) (4)	
User entered '25 Oct 2020' reason for change: Data Entry Error	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	
User entered '26 Oct 2020'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered '0'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered missing code ND - Not Done.	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User entered '%'	System	26 Oct 2020 18:44:57



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered missing code ND - Not Done.	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
	(b) (4)	
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:00:41
User closed query 'Please clarify. Source progress notes dated 26Oct2020 indicates patient reports onset of dry cough on 10/25. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 23:00:39
Query 'Please clarify. Source progress notes dated 26Oct2020 indicates patient reports onset of dry cough on 10/25. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	11 Mar 2021 22:40:29
DataPoint Un-verified.	Matthew Musikanth (b) (4)	11 Mar 2021 22:40:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	11 Mar 2021 22:40:23
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:19:16
User opened query 'Please clarify. Source progress notes dated 26Oct2020 indicates patient reports onset of dry cough on 10/25. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 22:19:14
User entered 'None (None)'	Matthew Musikanth (b) (4)	26 Oct 2020 18:44:57

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:19:29
User entered 'Moderate (Moderate)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:12:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:50
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:44:57
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User entered 'Day 2 (Day 2)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered '26 Oct 2020'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered '0'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered '98'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User entered '%'	System	26 Oct 2020 18:47:37

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered '98.5' F	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:23:47
User entered 'Mild (Mild)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:23:45
User entered 'Mild (Mild)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
	(b) (4)	
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User closed query 'Please clarify. Source indicates moderate headache on symptom log dated 26Oct2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 23:04:44
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:42
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Matthew Musikanth	11 Mar 2021 23:04:15
Query 'Please clarify. Source indicates moderate headache on symptom log dated 26Oct2020. Please confirm and update as necessary.' answered with '26Oct2021 sources indicates mild "Dry" cough. Updated' (Site from CRA).	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Matthew Musikanth	11 Mar 2021 22:41:45
User opened query 'Please clarify. Source indicates moderate headache on symptom log dated 26Oct2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	11 Mar 2021 22:23:42
	(b) (4), (b) (6)	
	(b) (4)	
	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered 'Mild (Mild)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:12:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:04:51
User entered 'None (None)'	Matthew Musikanth	26 Oct 2020 18:47:37
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User entered 'Day 3 (Day 3)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:12
User entered '27 Oct 2020'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:10
User entered '0'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:09
User entered '98'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User entered '%'	System	27 Oct 2020 21:00:11

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:07
User entered '98.9' F	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:04
User entered 'None (None)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:25:51
User entered 'Mild (Mild)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:26:00
User entered 'Mild (Mild)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:23:28
User entered 'None (None)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:26:23
User entered 'Moderate (Moderate)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:26:29
User entered 'Moderate (Moderate)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:26:30
User entered 'Moderate (Moderate)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:26:37
User entered 'Moderate (Moderate)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:26:45
User entered 'Mild (Mild)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:26:48
User entered 'Mild (Mild)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:27:00
User entered 'Moderate (Moderate)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:01:55
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Matthew Musikanth	11 Mar 2021 22:43:00
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:27:18
User entered 'Mild (Mild)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:27:20
User entered 'Mild (Mild)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:27:22
User entered 'None (None)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:12:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:26:51
User entered 'Mild (Mild)'	Matthew Musikanth	27 Oct 2020 21:00:11
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
User entered 'Day 4 (Day 4)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:16
User entered '28 Oct 2020'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:18
User entered '0'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:28:39
User entered '99'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User entered '%'	System	28 Oct 2020 23:40:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:28:40
User entered '98.9' F	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:02:27
User entered 'None (None)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:28:45
User entered 'Mild (Mild)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:28:51
User entered 'Mild (Mild)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:20:44
User entered 'None (None)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:29:13
User entered 'Severe (Severe)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:29:23
User entered 'Moderate (Moderate)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:29:25
User entered 'Moderate (Moderate)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:29:27
User entered 'Mild (Mild)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:29:31
User entered 'Mild (Mild)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:29:33
User entered 'Mild (Mild)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:29:41
User entered 'Moderate (Moderate)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:20:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Matthew Musikanth	15 Mar 2021 20:16:20
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:29:57
User entered 'None (None)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	



US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:29:59
User entered 'None (None)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:30:01
User entered 'None (None)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:12:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:29:36
User entered 'Moderate (Moderate)'	Matthew Musikanth	28 Oct 2020 23:40:06
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:30:45
User entered '26 Oct 2020'	Matthew Musikanth	26 Oct 2020 18:43:34
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:30:45
User entered 'Yes (Y)'	Matthew Musikanth	26 Oct 2020 18:43:34
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:57
	(b) (4)	
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:00:05
User closed query 'Source lab result indicates 'not detected' signed by PI on 29Oct2020. Please update.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 23:00:03
Query 'Source lab result indicates 'not detected' signed by PI on 29Oct2020. Please update.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	11 Mar 2021 22:55:39
DataPoint Un-verified.	Matthew Musikanth (b) (4)	11 Mar 2021 22:55:33
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	11 Mar 2021 22:55:33
User opened query 'Source lab result indicates 'not detected' signed by PI on 29Oct2020. Please update.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 22:31:46
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:30:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 02:38:52
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	Matthew Musikanth (b) (4)	26 Oct 2020 18:43:39
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 18:43:34
User entered empty.	Matthew Musikanth (b) (4)	26 Oct 2020 18:43:34

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:30:45
User entered '26 Oct 2020'	Matthew Musikanth	26 Oct 2020 18:43:34
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:30:45
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Matthew Musikanth (b) (4)	26 Oct 2020 18:43:34



US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:30:45
User entered empty.	Matthew Musikanth	26 Oct 2020 18:43:34
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:30:45
User entered 'No (N)'	Matthew Musikanth	26 Oct 2020 18:43:34
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:30:45
User entered empty.	Matthew Musikanth	26 Oct 2020 18:43:34
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:30:45
User entered empty.	Matthew Musikanth	26 Oct 2020 18:43:34
	(b) (4)	

US3112128

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:12:21

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:23:57
User entered '0'	System	11 Mar 2021 22:55:33

**US3112128**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User accepted default value 'Day 3 (Day 3)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

US3112128

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

US3112128

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:12:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User closed query 'Per GCL Lab Recon: GCL is not reporting receiving a sample for 20Sep2020. Please clarify the sample was shipped.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:47:16
Query 'Per GCL Lab Recon: GCL is not reporting receiving a sample for 20Sep2020. Please clarify the sample was shipped.' answered with 'Confirmed. Results are in Preclarus portal.' (Site from DM).	Matthew Musikanth (b) (4)	27 Oct 2020 21:02:26
User opened query 'Per GCL Lab Recon: GCL is not reporting receiving a sample for 20Sep2020. Please clarify the sample was shipped.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 03:32:29
User entered '20 Sep 2020'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58



**US3112128**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 15:12:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User accepted default value 'Day 5 (Day 5)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

US3112128

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

**US3112128**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 15:12:21**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User entered empty.	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

**US3112128**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:12:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User accepted default value 'Day 7 (Day 7)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

US3112128

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

**US3112128**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:12:21**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User entered empty.	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

**US3112128**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 15:12:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User accepted default value 'Day 9 (Day 9)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58



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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:12:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User entered empty.	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

**US3112128**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:12:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User accepted default value 'Day 14 (Day 14)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

**US3112128**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:12:21**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User entered empty.	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

**US3112128**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 15:12:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User accepted default value 'Day 21 (Day 21)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

US3112128

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

**US3112128**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 15:12:21**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User entered empty.	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

**US3112128**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:12:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User accepted default value 'Day 28 (Day 28)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58



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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

**US3112128**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:12:21**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:32
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:21:10
User entered empty.	Matthew Musikanth (b) (4)	16 Oct 2020 18:46:58

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:12:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

**US3112128**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:12:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:12:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26



US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:12:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:12:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:12:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

**US3112128**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 15:12:21**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

**US3112128**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:12:21**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26



US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:12:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:12:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:12:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:12:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:12:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:12:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:34:14
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 23:25:26

US3112128

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:42:58



US3112128

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:05
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	16 Oct 2020 18:42:58

US3112128

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:05
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:42:58

**US3112128**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:12:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:14
User entered 'SICKD1'	System	16 Oct 2020 18:42:58

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:54
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:54
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:54
User entered '09:18'	Matthew Musikanth (b) (4)	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User entered '18 Sep 2020 09:18'	System	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:54
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	16 Oct 2020 18:43:53
DataPoint set to visible.	System	16 Oct 2020 18:42:58



US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:54
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	16 Oct 2020 18:43:53
DataPoint set to visible.	System	16 Oct 2020 18:42:58

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:54
User entered '97.9' F	Matthew Musikanth (b) (4)	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:54
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:54
User entered empty.	Matthew Musikanth (b) (4)	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:54
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Oct 2020 18:44:13
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Oct 2020 18:44:13
User entered '90' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	16 Oct 2020 18:44:13
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Oct 2020 18:43:53
User entered '16'	Matthew Musikanth (b) (4)	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User entered 'bpm'	System	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:54
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Oct 2020 18:44:13
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Oct 2020 18:44:13
User entered '16' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	16 Oct 2020 18:44:13
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Oct 2020 18:43:53
User entered '90'	Matthew Musikanth (b) (4)	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User entered 'breaths/min'	System	16 Oct 2020 18:43:53



US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:54
User entered '148'	Matthew Musikanth (b) (4)	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User entered 'mmHg'	System	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:18:54
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 06:36:21
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per Invest.' (Site from System).	Matthew Musikanth (b) (4)	16 Oct 2020 18:44:22
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		16 Oct 2020 18:43:53
User entered '101'	Matthew Musikanth (b) (4)	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User entered 'mmHg'	System	16 Oct 2020 18:43:53

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18

US3112128

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:19:18
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:44:31

US3112128

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:19:18
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	16 Oct 2020 18:44:31



US3112128

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:12:21

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:27
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:19:34
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Oct 2020 18:44:37

US3112128

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:12:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:27
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:19:34
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	16 Oct 2020 18:44:37

US3112128

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:14
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:47:32
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' answered with 'saliva collection dated 28oct2020 is in EDC' (Site from DM).	Natalie Moy (b) (4) (b) (4)	23 Nov 2020 18:22:50
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:56:17
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 18:48:20

US3112128

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:14
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	26 Oct 2020 18:48:20

US3112128

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:14
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	26 Oct 2020 18:48:20

**US3112128**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:12:21**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	26 Oct 2020 18:48:20

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:09

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:49
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:09



US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:49
User entered '10:10'	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:09

**US3112128**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 10:10'	System	26 Oct 2020 18:49:09

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:09
DataPoint set to visible.	System	26 Oct 2020 18:48:20

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:09
DataPoint set to visible.	System	26 Oct 2020 18:48:20

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:49
User entered '98.5' F	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:09

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:49
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:09

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:49
User entered empty.	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:09

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:49
User entered '106'	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:09



**US3112128**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Oct 2020 18:49:09

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:49
User entered '18'	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:09

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Oct 2020 18:49:09

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:49
User entered '134'	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:09

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Oct 2020 18:49:09

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:49
User entered '82'	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:09

US3112128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Oct 2020 18:49:09

US3112128

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:54
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:17



US3112128

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:32:54
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:17

US3112128

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:12:21

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:33:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:26

US3112128

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 15:12:21**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:33:05
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	26 Oct 2020 18:49:26

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:19:56
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:19:56
User entered empty.	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:19:56
User entered empty.	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:50:39

**US3112128**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:12:21**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	25 Feb 2021 18:50:39

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:03
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:24



US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:03
User entered empty.	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:24

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:03
User entered empty.	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:24

**US3112128**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 18:54:24

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:03
User entered empty.	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:24

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:03
User entered empty.	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:24

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:03
User entered empty.	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:24

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:03
User entered empty.	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:24

**US3112128**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 18:54:24



US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:03
User entered empty.	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:24

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 18:54:24

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:03
User entered empty.	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:24

**US3112128**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 18:54:24

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:03
User entered empty.	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:24

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 18:54:24

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:09
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:29

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:09
User entered empty.	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:29



US3112128

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 15:12:21**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:15
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:37

US3112128

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:12:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:20:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 18:54:37

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:13:57
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 20:50:20

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:13:57
User entered '22 Jan 2021' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 20:51:07
User entered '25 Jan 2021'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 20:50:20

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:13:57
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 20:50:20

**US3112128**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:12:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 20:50:20

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:21

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:15:02
User entered '22 Jan 2021'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 20:51:19

**US3112128**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:12:21**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:28:28
User entered '0'	Brenda Grande (b) (4) (b) (4)	15 Mar 2021 16:48:03
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:43:57



US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:15:05
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 20:51:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Jan 2021 20:51:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 20:51:41
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 20:51:19
User entered empty.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 20:51:19

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:28:28
User entered 'Amendment 6 or later (Amendment 6 or later)'	Brenda Grande (b) (4) (b) (4)	15 Mar 2021 16:48:03
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:43:57

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:21

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:15:08
User entered '22 Jan 2021'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 20:51:19

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:27:48
User closed query 'Please clarify. Source IRT document indicates subject received mRNA-1273. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 16:27:47
Query 'Please clarify. Source IRT document indicates subject received mRNA-1273. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	15 Mar 2021 16:48:20
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	15 Mar 2021 16:48:03
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	15 Mar 2021 16:48:03
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:18:49
User opened query 'Please clarify. Source IRT document indicates subject received mRNA-1273. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 23:18:41
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 20:51:19

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:27:54
User closed query 'Please clarify. Source IRT document indicates dose 1 was mRNA-1273. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 16:27:51
Query 'Please clarify. Source IRT document indicates dose 1 was mRNA-1273. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	15 Mar 2021 16:48:28
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	15 Mar 2021 16:48:03
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	15 Mar 2021 16:48:03
User opened query 'Please clarify. Source IRT document indicates dose 1 was mRNA-1273. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 23:19:34
Query 'Please clarify. Source IRT document that dose 1 was mRNA-1273. Please confirm and update as necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 23:18:53
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:18:51
User opened query 'Please clarify. Source IRT document that dose 1 was mRNA-1273. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 23:17:34
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 20:51:19

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:28:06
User closed query 'Please clarify. Source IRT document that dose 2 was N/A. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 16:27:56
Query 'Please clarify. Source IRT document that dose 2 was N/A. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	15 Mar 2021 16:48:35
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	15 Mar 2021 16:48:03
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	15 Mar 2021 16:48:03
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:19:37
User opened query 'Please clarify. Source IRT document that dose 2 was N/A. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 23:17:01
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 20:51:19

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:17:03
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 20:51:19

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered empty.	System	15 Mar 2021 16:48:03
User entered '1'	System	26 Jan 2021 20:51:19



US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered 'I'	System	26 Jan 2021 20:51:41
User entered empty.	System	26 Jan 2021 20:51:19

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered empty.	System	26 Jan 2021 21:05:42
DataPoint set to visible.	System	26 Jan 2021 20:51:41

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered empty.	System	26 Jan 2021 21:05:42
DataPoint set to visible.	System	26 Jan 2021 20:51:41

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42



US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '22 Jan 2021'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '14:02'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered '22 Jan 2021 14:02'	System	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '98.3' F	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered empty.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '118'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42



US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered 'bpm'	System	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '16'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered 'breaths/min'	System	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '114'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered 'mmHg'	System	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '76'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered 'mmHg'	System	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42



US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered empty.	System	26 Jan 2021 21:05:42
DataPoint set to visible.	System	26 Jan 2021 20:51:41

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '22 Jan 2021'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '15:35'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered '22 Jan 2021 15:35'	System	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '98.2' F	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42



US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered empty.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '110'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered 'bpm'	System	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '16'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered 'breaths/min'	System	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '112'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered 'mmHg'	System	26 Jan 2021 21:05:42



US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:20:47
User entered '68'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered 'mmHg'	System	26 Jan 2021 21:05:42

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:21:05
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:06:58

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:21:05
User entered '22 Jan 2021'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:06:58

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:21:57
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:07:35

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:21:57
User entered '22 Jan 2021'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:07:35

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:21:57
User entered 'Urine (URINE)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:07:35

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:21:57
User entered 'Negative (NEGATIVE)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:07:35



US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
Query 'Per CDM: Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' canceled (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 00:19:37
User opened query 'Per CDM: Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:05:48
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:21:57
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:07:35

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:21:57
User entered empty.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:07:35

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:21:57
User entered empty.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:07:35

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered empty.	System	26 Jan 2021 21:07:35

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:22:22
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:09:12

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:22:22
User entered empty.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:09:12

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

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)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:22:22
User entered empty.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:09:12

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered 'mRNA-1273'	System	26 Jan 2021 21:09:12
DataPoint set to visible.	System	26 Jan 2021 20:51:41



US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:22:22
User entered '22 Jan 2021'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:09:12

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:22:22
User entered '15:04'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:09:12

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered '22 Jan 2021 15:04'	System	26 Jan 2021 21:09:12

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:22:22
User entered 'Left Arm (LEFT ARM)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:09:12

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:22:22
User entered 'ONCE'	System	26 Jan 2021 21:09:12

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered 'INTRAMUSCULAR'	System	26 Jan 2021 21:09:12

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:25:40
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:12:43

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:25:40
User entered '22 Jan 2021'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:12:43



US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:25:40
User entered '14:25'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:12:43

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered '22 Jan 2021 14:25'	System	26 Jan 2021 21:12:43

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:12:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:25:22
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:13:02

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:12:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:25:22
User entered '22 Jan 2021'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:13:02

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:12:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:25:22
User entered '14:12'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:13:02

**US3112128**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:12:21**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered '22 Jan 2021 14:12'	System	26 Jan 2021 21:13:02

US3112128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:25:45
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 21:13:13

**US3112128**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:49:23
User entered '1'	System	26 Jan 2021 21:13:13



US3112128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:28:14
User entered 'Yes (Y)'	Matthew Musikanth	29 Jan 2021 22:03:21
	(b) (4)	

US3112128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:28:14
User entered '29 Jan 2021'	Matthew Musikanth (b) (4)	29 Jan 2021 22:03:21

US3112128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:28:14
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	29 Jan 2021 22:03:21

US3112128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:28:14
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 22:03:21

US3112128

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:28:20
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Jan 2021 22:03:13

**US3112128**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:14
User entered 'I'	System	29 Jan 2021 22:03:13

**US3112128**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:14
User entered '1'	System	29 Jan 2021 22:03:13
DataPoint set to visible.	System	29 Jan 2021 22:03:13

US3112128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:08:19
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:07:12
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:12:24



US3112128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:25
User entered '22 Feb 2021' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:08:19
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:07:12
User entered '22 Feb 2021'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:12:24

US3112128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:25
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). User entered 'Clinic (Clinic)' reason for change: Data Entry Error	System	05 Mar 2021 16:08:29
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:08:29
User entered 'Clinic (Clinic)'	System	05 Mar 2021 16:08:19
	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:07:12
	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:12:24

**US3112128**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:12:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered 'OLD29'	System	23 Feb 2021 00:12:24

US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 15:48:28

US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:11
User entered '22 Feb 2021'	(b) (4), (b) (6)	16 Apr 2021 15:48:28

US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:11
User entered '13:13'	(b) (4), (b) (6)	16 Apr 2021 15:48:28

**US3112128**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered '22 Feb 2021 13:13'	System	16 Apr 2021 15:48:28

US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:11
User entered '98.7' F	(b) (4), (b) (6)	16 Apr 2021 15:48:28



US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:11
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Apr 2021 15:48:28

US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:11
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 15:48:28

US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:11
User entered '104'	(b) (4), (b) (6)	16 Apr 2021 15:48:28

**US3112128**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered 'bpm'	System	16 Apr 2021 15:48:28

US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:11
User entered '16'	(b) (4), (b) (6)	16 Apr 2021 15:48:28

US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered 'breaths/min'	System	16 Apr 2021 15:48:28

US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:11
User entered '128'	(b) (4), (b) (6)	16 Apr 2021 15:48:28

US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered 'mmHg'	System	16 Apr 2021 15:48:28



US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:11
User entered '78'	(b) (4), (b) (6)	16 Apr 2021 15:48:28

US3112128

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered 'mmHg'	System	16 Apr 2021 15:48:28

**US3112128**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28

**US3112128**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:09:28
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 22:08:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 22:08:06
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:08:06
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 22:07:44
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:07:44
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered '22 Feb 2021' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:09:28
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:07:44
User entered '22 Feb 2021'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered '13:13' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:09:28
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:07:44
User entered '13:13'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17



**US3112128**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered '22 Feb 2021 13:13'	System	05 Mar 2021 16:09:28
User entered empty.	System	24 Feb 2021 22:07:44
User entered '22 Feb 2021 13:13'	System	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered '98.7' F reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:09:28
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:07:44
User entered '98.7' F	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered 'Oral (Oral)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:09:28
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:07:44
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered '104' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:09:28
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:07:44
User closed query 'Pulse reported is out of range < 45 System or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		23 Feb 2021 00:14:33
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	23 Feb 2021 00:14:33
User entered '104' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:33
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	23 Feb 2021 00:14:17
User entered '16'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered 'bpm'	System	05 Mar 2021 16:09:28
User entered empty.	System	24 Feb 2021 22:07:44
User entered 'bpm'	System	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered '16' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:09:28
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:07:44
User entered '16'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered 'breaths/min'	System	05 Mar 2021 16:09:28
User entered empty.	System	24 Feb 2021 22:07:44
User entered 'breaths/min'	System	23 Feb 2021 00:14:17



US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered '128' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:09:28
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:07:44
User entered '128'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered 'mmHg'	System	05 Mar 2021 16:09:28
User entered empty.	System	24 Feb 2021 22:07:44
User entered 'mmHg'	System	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered '78' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:09:28
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:07:44
User entered '78'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered 'mmHg'	System	05 Mar 2021 16:09:28
User entered empty.	System	24 Feb 2021 22:07:44
User entered 'mmHg'	System	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 22:08:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 22:08:06
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:08:06
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 22:07:44
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:07:44
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17



**US3112128**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:12:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered empty.	System	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

**US3112128**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:12:21**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered empty.	System	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered empty.	System	23 Feb 2021 00:14:17



US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered empty.	System	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:56
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered empty.	System	23 Feb 2021 00:14:17

US3112128

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:17
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	11 Mar 2021 23:40:21
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	11 Mar 2021 23:40:13
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	11 Mar 2021 23:40:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:09:56
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:44

US3112128

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:17
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	11 Mar 2021 23:40:21
User entered '22 Feb 2021' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:09:56
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:44

US3112128

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:24
User closed query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.'" (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 20:57:07
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 23:24:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 23:24:04
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 23:24:04
Query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.'" answered with 'visit did not occur' (Site from DM).	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 23:23:53
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 23:23:36
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 23:23:36
User opened query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.'" (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 09:45:37
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:49

US3112128

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:24
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:49



US3112128

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:24
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:49

US3112128

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:24
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:49

US3112128

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:24
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:49

US3112128

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:24
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:49

US3112128

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:12:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:24
User entered empty.	Natalie Moy (b) (4) (b) (4)	23 Feb 2021 00:14:49

**US3112128**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:12:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered empty.	System	23 Feb 2021 00:14:49

US3112128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:37
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:08:11

US3112128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:37
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		24 Feb 2021 23:22:58
User entered 'Other (OTHER)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 23:22:58
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	24 Feb 2021 22:08:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:08:11



US3112128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

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)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:37
User entered 'SUBJECT CAME IN FOR OPEN LABEL 1 MONTH FOLLOW UP BECAUSE SHE PREVIOUSLY RECEIVED 1ST DOSE THEN CAME INTO O-L DECISION VISIT APPROVED BY STUDY AND GOT 2ND DOSE.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	11 Mar 2021 23:40:50
User entered 'SUBJECT CAME IN FOR OPEN LABEL 1 MONTH FOLLOW UP BECAUSE SHE PREVIOUSLY RECEIVED 1ST DOSE THEN CAME INTO O-L DECISION VISIT APPROVED BY STUDY AND GOT 2NDE DOSE.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	11 Mar 2021 23:40:37
User entered 'SUBJECT CAME IN FOR Open Label ! month follow up BECAUSE SHE PREVIOUSLY RECEIVED 1ST DOSE THEN CAME INTO O-L DECISION VISIT APPROVED BY STUDY AND GOT 2NDE DOSE.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:05
User closed query 'Per CDM: Since the reason is other. Please update the reason in this data point.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 22:54:16
Query 'Per CDM: Since the reason is other. Please update the reason in this data point.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 15:48:41
User entered 'subject came in for v3 day 57 O-L because she previously received 1st dose then came into O-L decision visit approved by study and got 2nde dose.' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	25 Feb 2021 15:47:53
User opened query 'Per CDM: Since the reason is other. Please update the reason in this data point.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 05:39:53
User entered empty.	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:08:11

US3112128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
DataPoint set to visible.	System	15 Mar 2021 16:48:03
User entered empty.	System	24 Feb 2021 22:08:11
DataPoint set to invisible.	System	29 Jan 2021 22:03:13

US3112128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:37
User entered empty.	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:08:11

US3112128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:37
User entered empty.	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:08:11

US3112128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered empty.	System	24 Feb 2021 22:08:11

US3112128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:37
User entered empty.	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:08:11

US3112128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:44:37
User entered empty.	System	24 Feb 2021 22:08:11

US3112128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered empty.	System	24 Feb 2021 22:08:11



US3112128

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 15:49:00

US3112128

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:02:22
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:44
User entered '22 Feb 2021'	(b) (4), (b) (6)	16 Apr 2021 15:49:00

US3112128

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:52:44
User entered '13:16'	(b) (4), (b) (6)	16 Apr 2021 15:49:00

**US3112128**

**Folder: OL-D29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:12:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered '22 Feb 2021 13:16'	System	16 Apr 2021 15:49:00

US3112128

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:02
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:08:14

**US3112128**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:34:28
User entered 'I'	System	24 Feb 2021 22:08:14

US3112128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:08
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:09:06

US3112128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:08
User entered empty.	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:09:06



US3112128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:08
User entered empty.	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:09:06

US3112128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:08
User entered 'Not needed as per Table 22 of protocol.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 17:04:14
User entered empty.	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:09:06

US3112128

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:11
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:09:10

**US3112128**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:12:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 22:09:10

US3112128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Please add comment "not needed per table 22 in the protocol". ' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 16:07:43
Query 'Please add comment "not needed per table 22 in the protocol". ' answered with 'no location to enter comment ' (Site from CRA).	Brenda Grande (b) (4)	06 Apr 2021 17:59:19
User opened query 'Please add comment "not needed per table 22 in the protocol". ' (Site from CRA).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	05 Apr 2021 20:23:35
	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:17
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:12:09
User entered 'Yes (Y)'	Brenda Grande (b) (4)	24 Feb 2021 22:09:21
	(b) (4)	

US3112128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:17
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:12:09
User entered '22 Feb 2021'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:09:21

US3112128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:17
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:12:09
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:09:21

**US3112128**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:12:21**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	24 Feb 2021 22:09:21



US3112128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:20
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:53
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:14

US3112128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:20
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:53
User entered '22 Feb 2021'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:14

US3112128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:20
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:53
User entered '13:13'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:14

**US3112128**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:11:53
User entered '22 Feb 2021 13:13'	System	24 Feb 2021 22:10:14

US3112128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:20
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:53
User entered '98.7' F	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:14

US3112128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:20
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:53
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:14

US3112128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:20
User entered empty.	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:14

US3112128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:20
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:53
User entered '104'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:14



**US3112128**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:11:53
User entered 'bpm'	System	24 Feb 2021 22:10:14

US3112128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:20
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:53
User entered '16'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:14

**US3112128**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:11:53
User entered 'breaths/min'	System	24 Feb 2021 22:10:14

US3112128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:20
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:53
User entered '128'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:14

**US3112128**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:11:53
User entered 'mmHg'	System	24 Feb 2021 22:10:14

US3112128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:20
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:53
User entered '78'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:14

**US3112128**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:12:21**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:11:53
User entered 'mmHg'	System	24 Feb 2021 22:10:14

US3112128

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:23
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:36
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:32



US3112128

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:23
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:36
User entered '22 Feb 2021'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:32

US3112128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04MAR2021 is reported under OL-D3 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under OL-D57 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 04:38:27
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04MAR2021 is reported under OL-D3 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under OL-D57 Visit on Immunogenicity Assessment page.' answered with 'Sample was collected under OL-D29. No sample was collected on OL-D57' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 16:48:17
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04MAR2021 is reported under OL-D3 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under OL-D57 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:40:06
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:51:34
User closed query 'Source listed that assessment was not done. Please update EDC. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:07:12
	(b) (4), (b) (6)	07 Apr 2021 16:07:09
Query 'Source listed that assessment was not done. Please update EDC. ' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4)	05 Apr 2021 22:39:05
DataPoint Un-verified.	Brenda Grande (b) (4)	05 Apr 2021 22:38:51
Signature has been broken.	Brenda Grande (b) (4)	05 Apr 2021 22:38:51
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4)	05 Apr 2021 22:38:51
User opened query 'Source listed that assessment was not done. Please update EDC. ' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 20:21:35

US3112128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:20:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
User closed query 'Per GCL Lab Recon: Immuno: Sample dated 22 FEB 2021 is recorded under OL-D57 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Thank you.	(b) (4), (b) (6)	30 Mar 2021 15:17:01
' (Site from DM). Query 'Per GCL Lab Recon: Immuno: Sample dated 22 FEB 2021 is recorded under OL-D57 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Thank you.	Brenda Grande (b) (4) (b) (4)	25 Mar 2021 20:35:30
' answered with 'updated' (Site from DM). DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	25 Mar 2021 20:35:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	25 Mar 2021 20:35:17
User opened query 'Per GCL Lab Recon: Immuno: Sample dated 22 FEB 2021 is recorded under OL-D57 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Thank you.	(b) (4), (b) (6)	22 Mar 2021 13:57:13
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:27
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:25
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:45

US3112128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	08 Apr 2021 22:51:34
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:07:09
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	05 Apr 2021 22:38:51
Signature has been broken.	Brenda Grande (b) (4) (b) (4)	05 Apr 2021 22:38:51
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	05 Apr 2021 22:38:51
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:20:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	25 Mar 2021 20:35:17
User entered '22 Mar 2021' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	25 Mar 2021 20:35:17
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:27
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:25
User entered '22 Feb 2021'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:45

US3112128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	08 Apr 2021 22:51:34
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:07:09
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	05 Apr 2021 22:38:51
Signature has been broken.	Brenda Grande (b) (4) (b) (4)	05 Apr 2021 22:38:51
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	05 Apr 2021 22:38:51
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:20:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	25 Mar 2021 20:35:17
User entered '13:16' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	25 Mar 2021 20:35:17
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:45:27
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:11:25
User entered '13:16'	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 22:10:45

**US3112128**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:12:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 22:38:51
User entered '22 Mar 2021 13:16'	System	25 Mar 2021 20:35:17
User entered empty.	System	05 Mar 2021 16:11:25
User entered '22 Feb 2021 13:16'	System	24 Feb 2021 22:10:45

US3112128

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:12:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:16
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Sep 2020 20:39:06

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:12:21**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User closed query 'Per MM: Please update event term to reflect etiology/medical diagnosis if known.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:12:37
User closed query 'Per MM: Please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:20:25
Query 'Per MM: Please update event term to reflect etiology/medical diagnosis if known.' answered with 'just fever' (Site from DM).	Natalie Moy (b) (4) (b) (4)	15 Oct 2020 20:42:17
Query 'Per MM: Please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' answered with 'not symptom of covid ' (Site from DM).	Natalie Moy (b) (4) (b) (4)	15 Oct 2020 20:41:44
User opened query 'Per MM: Please update event term to reflect etiology/medical diagnosis if known.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:59:02
User opened query 'Per MM: Please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:58:26
User coded data point as SOC: General disorders and administration site conditions, HLG: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:41:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:41:46
Data point term sent to Coder	System	29 Sep 2020 20:40:27
User entered 'Fever'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered 'No (N)'	Matthew Musikanth	29 Sep 2020 20:40:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered '13 Sep 2020'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered empty.	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User entered empty.	System	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered '13 Sep 2020'	Matthew Musikanth	29 Sep 2020 20:40:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered empty.	Matthew Musikanth	29 Sep 2020 20:40:16
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User entered empty.	System	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth	29 Sep 2020 20:40:16
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered empty.	Matthew Musikanth	29 Sep 2020 20:40:16
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered empty.	Matthew Musikanth	29 Sep 2020 20:40:16
	(b) (4)	

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered empty.	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered empty.	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	29 Sep 2020 20:40:16
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered 'None (NONE)'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered 'l'	Matthew Musikanth	29 Sep 2020 20:40:16
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

US3112128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth	29 Sep 2020 20:40:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered empty.	Matthew Musikanth	29 Sep 2020 20:40:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:51
User entered empty.	Matthew Musikanth (b) (4)	29 Sep 2020 20:40:16



**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User entered '0'	System	29 Sep 2020 20:40:16

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51
User entered '0'	System	29 Sep 2020 20:40:16

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:37:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain lower, LLT: Right lower quadrant pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 13:08:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 13:08:01
Data point term sent to Coder	System	04 Dec 2020 19:52:44
Coding entries removed.	Matthew Musikanth (b) (4)	04 Dec 2020 19:52:08
User entered 'Intermittent RIGHT LOWER QUADRANT PAIN' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	04 Dec 2020 19:52:08
User closed query 'Per MM: Please update event term to reflect etiology/medical diagnosis if known.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:12:50
Query 'Per MM: Please update event term to reflect etiology/medical diagnosis if known.' answered with 'no diagnosis ' (Site from DM).	Natalie Moy (b) (4) (b) (4)	15 Oct 2020 20:42:50
User opened query 'Per MM: Please update event term to reflect etiology/medical diagnosis if known.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:01:20
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain lower, LLT: Right lower quadrant pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:03:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:03:39
Data point term sent to Coder	System	29 Sep 2020 21:02:11
User entered 'Right Lower quadrant pain'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:12:21**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered '12 Aug 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 23:21:14
User entered '12 Sep 2020'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered empty.	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:12:21**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 02:19:35
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'Updated AE term as pain seems to come and go. PI approved. ' (Site from DM).	Matthew Musikanth (b) (4)	04 Dec 2020 19:52:38
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 04:53:26
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered empty.	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:12:21**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered empty.	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:12:21**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

US3112128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

US3112128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

US3112128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered empty.	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered empty.	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

US3112128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered empty.	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

US3112128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered empty.	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

US3112128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23



US3112128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 21:01:37
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 21:01:23
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:29:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
User closed query 'Per CDM: The primary reason for discontinuation is "AE" however, "action taken with investigational product" is None. Please refer to Page 55 of the CCGs, under primary reason for treatment discontinuation and reconcile accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 04:20:09
Query 'Per CDM: The primary reason for discontinuation is "AE" however, "action taken with investigational product" is None. Please refer to Page 55 of the CCGs, under primary reason for treatment discontinuation and reconcile accordingly.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	25 Mar 2021 21:01:14
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	25 Mar 2021 21:00:41
Signature has been broken.	Brenda Grande (b) (4) (b) (4)	25 Mar 2021 21:00:41
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	25 Mar 2021 21:00:41
User opened query 'Per CDM: The primary reason for discontinuation is "AE" however, "action taken with investigational product" is None. Please refer to Page 55 of the CCGs, under primary reason for treatment discontinuation and reconcile accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 12:15:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered 'None (NONE)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:37
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User closed query 'Per DM CLR - RQ: Site's response noted. However, please confirm what symptom did the subject experienced on 12AUG2020 warranting to go to the ER. If the symptom was related to this AE, then that should be the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 00:35:49
Query 'Per DM CLR - RQ: Site's response noted. However, please confirm what symptom did the subject experienced on 12AUG2020 warranting to go to the ER. If the symptom was related to this AE, then that should be the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' answered with 'per investigator AE start date is day of sx onset which is 12 SEP 2020' (Site from DM).	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 23:12:58
User opened query 'Per DM CLR - RQ: Site's response noted. However, please confirm what symptom did the subject experienced on 12AUG2020 warranting to go to the ER. If the symptom was related to this AE, then that should be the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 23:15:39
User closed query 'Per CDM Re-query: Response noted however, no corresponding medication was found to be recorded in the CM page matching the timeframe of this AE (12 SEP 2020- Ongoing). Kindly reconcile and update the data in CM page as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 02:19:07

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per CDM Re-query: Response noted however, no corresponding medication was found to be recorded in the CM page matching the timeframe of this AE (12 SEP 2020- Ongoing). Kindly reconcile and update the data in CM page as appropriate, else clarify.' answered with '12 Sep is onset of symptom, please see rx in conmed starting on 12Aug2020 that was taken for this AE when pain had become so unbearable that patient was seen in ER.' (Site from DM).	Matthew Musikanth (b) (4)	23 Nov 2020 22:43:03
User opened query 'Per CDM Re-query: Response noted however, no corresponding medication was found to be recorded in the CM page matching the timeframe of this AE (12 SEP 2020- Ongoing). Kindly reconcile and update the data in CM page as appropriate, else clarify.' (Site from DM).	Ipsita Abalokita (b) (4) (b) (4)	02 Nov 2020 19:53:35
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	Ipsita Abalokita (b) (4) (b) (4)	02 Nov 2020 19:53:35
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	27 Oct 2020 21:47:17
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:45:58
User entered 'I'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23



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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered '0'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:06:16
User entered empty.	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = WORK UP (-). Please review and verify what are these "WORK UP" and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:56:01
Query 'Per DM CLR: Narrative = WORK UP (-). Please review and verify what are these "WORK UP" and ensure that this is captured in the appropriate eCRF.' answered with 'workups in reference to diagnostic procedures' (Site from DM).	Brenda Grande (b) (4)	25 Mar 2021 21:00:16
User opened query 'Per DM CLR: Narrative = WORK UP (-). Please review and verify what are these "WORK UP" and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4)	21 Mar 2021 03:18:54
User signature succeeded.	(b) (4), (b) (6)	19 Mar 2021 20:20:54
DataPoint Verified.	Todd Simmons (b) (4)	(b) (4)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Mar 2021 00:19:57
User entered 'SEEN IN ER. oBTAINED MEDICAL RECORDS GIVEN ROCEPHIN, DOXY, CEFTIN PER MEDICAL RECORDS BUT NO DOSAGES OR DURATION REPORTED. PER PT. ALSO GIVEN MS . CT SCAN (-) WORKIP (-). NO OBVIOUS ETIOLOGY.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	12 Mar 2021 00:19:13
DataPoint Verified.	Matthew Musikanth (b) (4)	12 Mar 2021 00:19:13
User closed query 'Per DM CLR: SAE Narrative = PER PT. ALSO GIVEN MS . CT SCAN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 00:06:16
Query 'Per DM CLR: SAE Narrative = PER PT. ALSO GIVEN MS . CT SCAN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4)	19 Jan 2021 00:36:51
	(b) (4)	12 Jan 2021 23:17:33

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = PER PT. ALSO GIVEN MS . CT SCAN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 23:15:52
User entered 'Seen in ER. btained medical records given rocephin, doxy, ceftin per medical records but no dosages or duration reported. Per Pt. also given MS . Ct scan (-) workip (-). no obvious etiology.'	Matthew Musikanth (b) (4)	29 Sep 2020 21:01:23

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Sep 2020 21:01:23

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:12:21**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 21:01:23

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Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered empty; reason for change New Information	(b) (4)	22 Jan 2021 16:42:22
User entered	System	29 Dec 2020 16:55:47
'USA-US062-2020-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	29 Dec 2020 16:55:47



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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Cerebral injuries NEC, PT: Concussion, LLT: Concussion - version MedDRA\23.0.	Coder Import (b) (4)	28 Dec 2020 22:19:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Dec 2020 22:19:35
Data point term sent to Coder	System	28 Dec 2020 22:18:38
User entered 'Concussion'	Matthew Musikanth	28 Dec 2020 22:17:46
	(b) (4)	

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered '22 Nov 2020'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:12:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User entered empty.	System	28 Dec 2020 22:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:35:06
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	01 Feb 2021 22:03:57
User entered 'No (N)' reason for change: New Information	Brenda Grande (b) (4) (b) (4)	01 Feb 2021 22:03:51
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:30:47
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46



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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered '10 Jan 2021' reason for change: New Information	Brenda Grande (b) (4) (b) (4)	01 Feb 2021 22:03:51
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. (AE 3)' canceled (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 20:33:33
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. (AE 3)' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:30:58
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User entered empty.	System	28 Dec 2020 22:17:46

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	12 Jan 2021 18:34:42
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered '0' reason for change: Data Entry Error	Matthew Musikanth	12 Jan 2021 18:34:42
	(b) (4)	
User entered '1'	Matthew Musikanth	28 Dec 2020 22:17:46
	(b) (4)	



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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	12 Jan 2021 18:34:42
User entered '22 Nov 2020'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered empty; reason for change Data Entry Error	Matthew Musikanth	12 Jan 2021 18:34:42
	(b) (4)	
User entered '24 Nov 2020'	Matthew Musikanth	28 Dec 2020 22:17:46
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	12 Jan 2021 18:34:42
User entered 'No (N)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered '0'	Matthew Musikanth	28 Dec 2020 22:17:46
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46



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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Dec 2020 22:18:02
User entered '1' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	28 Dec 2020 22:18:02
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Dec 2020 22:17:46
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

US3112128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

US3112128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

US3112128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:12:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	01 Feb 2021 22:03:51
Query 'PV Query: Please provide the final event outcome when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. (AE3)' canceled (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 20:33:30
User opened query 'PV Query: Please provide the final event outcome when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. (AE3)' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:31:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:12:21**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

US3112128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:12:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:48:33
User entered 'Pt. experienced head injury weeks prior to admission to hospital. PI has updated seriousness as this was not the main complaint for hospital admission.	Matthew Musikanth (b) (4)	21 Jan 2021 16:10:17
PI UPDATED STATUS FROM SAE TO AE PER REVIEW OF MEDICAL RECORDS.' reason for change: Data Entry Error		
Query 'PV Query: Please provide additional details surrounding car accident. Does the car accident meet criteria for separate AE/SAE reporting? (AE3)' canceled (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 20:33:28
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. (AE3)' canceled (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 20:33:27
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. (AE3)' canceled (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 20:33:20
User entered 'PT. REPORTS HAVING EXPERIENCED A CONCUSSION AFTER A CAR ACCIDENT. SPENT SEVERAL DAYS IN HOSPITAL. PENDING MEDICAL RECORDS.	Matthew Musikanth (b) (4)	12 Jan 2021 18:34:42
PI updated status from SAE to AE per review of medical records.' reason for change: Data Entry Error		



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:12:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. (AE3)' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:32:02
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. (AE3)' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:31:28
User opened query 'PV Query: Please provide additional details surrounding car accident. Does the car accident meet criteria for separate AE/SAE reporting?' (AE3)' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:31:16
User entered 'Pt. reports having experienced a concussion after a car accident. Spent several days in hospital. Pending medical records.'	Matthew Musikanth (b) (4)	28 Dec 2020 22:17:46

US3112128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:12:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User entered '0'	System	12 Jan 2021 18:34:42
User entered '1'	System	28 Dec 2020 22:17:46

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:12:21**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User entered 'I'	System	28 Dec 2020 22:17:46

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:12:21**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:13
User entered '0'	System	28 Dec 2020 22:17:46

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered 'USA-US062-2020-mRNA-1273-P301000011'	(b) (4), (b) (6)	29 Dec 2020 16:56:37

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Diabetic complications, HLT: Diabetic complications NEC, PT: Diabetic ketoacidosis, LLT: Diabetic ketoacidosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Dec 2020 22:22:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Dec 2020 22:22:24
Data point term sent to Coder	System	28 Dec 2020 22:21:41
User entered 'Diabetic Ketoacidosis'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered 'No (N)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56



US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered 'No (N)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered '22 Nov 2020'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:12:21**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 22:20:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 22:21:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 22:21:46
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	28 Dec 2020 22:21:46
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 22:20:56
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered '22 Nov 2020'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:12:21**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 22:20:56



US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered 'Grade 4 (Grade 4)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered 'I'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	25 Jan 2021 04:15:11
User closed query 'PV Query: Please confirm if the subject was hospitalized for the life-threatening event of diabetic ketoacidosis. If so, please add as seriousness criteria.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:38:17
Query 'PV Query: Please confirm if the subject was hospitalized for the life-threatening event of diabetic ketoacidosis. If so, please add as seriousness criteria.' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	21 Jan 2021 16:08:18
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'dates added' (Site from System).	Matthew Musikanth (b) (4)	21 Jan 2021 16:07:10
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	21 Jan 2021 16:06:41
User entered '1' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Jan 2021 16:06:41
User opened query 'PV Query: Please confirm if the subject was hospitalized for the life-threatening event of diabetic ketoacidosis. If so, please add as seriousness criteria.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:30:10
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered '22 Nov 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Jan 2021 16:06:41
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 16:57:40
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'discharge summary has been faxed ' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	01 Feb 2021 21:59:54
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 17:24:28
User entered '24 Nov 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Jan 2021 16:06:41
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

US3112128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered 'I'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered '0'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User entered empty.	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:40:58
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 14:21:41
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Sent' (Site from Safety).	Matthew Musikanth (b) (4)	03 Feb 2021 22:07:39
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 21:52:04
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. (AE4)' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:38:40
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. (AE4)' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:38:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. (AE4)' answered with 'Treatment updated' (Site from Safety).	Matthew Musikanth (b) (4)	21 Jan 2021 17:07:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. (AE4)' answered with 'POC Glucose (mg/dL) 24Nov2020 (0809)- 127, 24Nov2020(0128) - 259, 23Nov2020(2113) - 236, 23Nov2020 (1749) - 141	Matthew Musikanth (b) (4)	21 Jan 2021 16:41:25
WBC (K/mcL) 24Nov2020 ( 0509)- 5.6, 23Nov2020 (0314) - 11.3, 22Nov2020 (1009)- 15.6		
Hematocrit (%) 24Nov2020 ( 0509)- 29.1, 23Nov2020 (0314) - 33.8, 22Nov2020 (1009)- 49.1		
PLT (K/mcL) 24Nov2020 ( 0509)- 174, 23Nov2020 (0314) - 246, 22Nov2020 (1009)- 362		
CO2 (mmol/L) 24Nov2020 ( 0509)- 18, 23Nov2020 (2213) - 17, 22Nov2020 (1118)- 19		
Anion GAP (mmol/L) 24Nov2020 ( 0509)- 6, 23Nov2020 (2213) - 5, 22Nov2020 (1118)- 3		
Albumin (g/dL) 24Nov2020 ( 0509)- 2.6, 23Nov2020 (0314) - 3.2, 22Nov2020 (1009)- 5.1' (Site from Safety).		
User entered 'PATIENT PRESENTED FOR DIABETIC KETOACIDOSIS.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Jan 2021 16:30:28
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. (AE4)' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 14:20:44

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. (AE4)' answered with 'no covid testing done ' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 23:57:50
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. (AE4)' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:29:45
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. (AE4)' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:29:28
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. (AE4)' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:27:54
User entered 'Patient presented for separate adverse event and was diagnosed with diabetic ketoacidosis. Pending medical records for further clarification.'	Matthew Musikanth (b) (4)	28 Dec 2020 22:20:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:12:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	28 Dec 2020 22:20:56



**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:12:21**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Dec 2020 22:20:56

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:12:21**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: White blood cell disorders, HLT: Leukocytoses NEC, PT: Leukocytosis, LLT: Leukocytosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 21:08:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 21:08:53
Data point term sent to Coder	System	21 Jan 2021 16:47:43
User entered 'UTI Leukocytosis'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

US3112128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

US3112128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

US3112128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered '22 Nov 2020'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

US3112128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User entered empty.	System	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered '01 Dec 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Jan 2021 17:05:48
User entered '24 Nov 2020'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:12:21**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User entered empty.	System	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

US3112128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered empty.	Matthew Musikanth	21 Jan 2021 16:46:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

US3112128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

US3112128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered 'I'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth	21 Jan 2021 16:46:52
	(b) (4)	



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Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:49:27
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User entered '0'	System	21 Jan 2021 16:46:52

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:12:21**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26
User entered 'I'	System	21 Jan 2021 16:46:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:12:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:26

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Candida infections, PT: Vulvovaginal candidiasis, LLT: Vaginal candidiasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 16:50:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 16:50:03
Data point term sent to Coder	System	21 Jan 2021 16:48:43
User entered 'Vaginal Candidiasis'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered 'Yes (Y)'	Matthew Musikanth	21 Jan 2021 16:47:47
	(b) (4)	



US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered '23 Nov 2020'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User entered empty.	System	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered '27 Nov 2020'	Matthew Musikanth	21 Jan 2021 16:47:47
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47



US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User entered empty.	System	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered empty.	Matthew Musikanth	21 Jan 2021 16:47:47
	(b) (4)	



**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:12:21**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered '0'	Matthew Musikanth	21 Jan 2021 16:47:47
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	21 Jan 2021 16:47:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47



US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered 'l'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:12:21**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:51:18
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:47:47

US3112128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:12:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User entered '0'	System	21 Jan 2021 16:47:47

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:12:21**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30
User entered 'I'	System	21 Jan 2021 16:47:47



**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:12:21**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:38:30

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:12:21**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: UTI - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 16:56:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 16:56:53
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: UTI - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 16:41:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 16:41:08
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 16:40:46
User entered 'UTI'	Matthew Musikanth	26 Feb 2021 16:40:43
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered 'Yes (Y)'	Matthew Musikanth	26 Feb 2021 16:40:43
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered 'No (N)'	Matthew Musikanth	26 Feb 2021 16:40:43
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User closed query 'Adverse Event Start Date is before System treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).		26 Feb 2021 16:41:03
User closed query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		26 Feb 2021 16:41:03
User entered '12 Aug 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	26 Feb 2021 16:41:03
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	26 Feb 2021 16:40:43
User opened query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		26 Feb 2021 16:40:43
User entered '12 Apr 2020'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User entered empty.	System	26 Feb 2021 16:40:43

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:12:21**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered '22 Aug 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	26 Feb 2021 16:41:03
User entered '22 Apr 2020'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered empty.	Matthew Musikanth	26 Feb 2021 16:40:43
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User entered empty.	System	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43



US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered empty.	Matthew Musikanth	26 Feb 2021 16:40:43
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered '0'	Matthew Musikanth	26 Feb 2021 16:40:43
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:20:21
User closed query 'Please clarify. Source indicates None. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 00:20:19
Query 'Please clarify. Source indicates None. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	12 Mar 2021 00:18:50
DataPoint Un-verified.	Matthew Musikanth (b) (4)	12 Mar 2021 00:18:44
User entered 'None (NONE)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	12 Mar 2021 00:18:44
User opened query 'Please clarify. Source indicates None. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 00:07:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered 'I'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:12:21**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

US3112128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:12:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:07:14
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 16:40:43

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:12:21**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User entered '0'	System	26 Feb 2021 16:40:43

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:12:21**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User entered 'I'	System	26 Feb 2021 16:40:43

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:12:21**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 20:04:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 20:04:53
Data point term sent to Coder	System	26 Feb 2021 20:03:59
User entered 'Viral syndrome'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:12:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered '25 Oct 2020'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User entered empty.	System	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered '19 Nov 2020'	Matthew Musikanth	26 Feb 2021 20:03:46
	(b) (4)	

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:12:21**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered empty.	Matthew Musikanth	26 Feb 2021 20:03:46
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:12:21**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User entered empty.	System	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered empty.	Matthew Musikanth	26 Feb 2021 20:03:46
	(b) (4)	



**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:12:21**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered '0'	Matthew Musikanth	26 Feb 2021 20:03:46
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered '0'	Matthew Musikanth	26 Feb 2021 20:03:46
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	26 Feb 2021 20:03:46
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46



US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered '0'	Matthew Musikanth	26 Feb 2021 20:03:46
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered 'I'	Matthew Musikanth	26 Feb 2021 20:03:46
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:12:21**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth	26 Feb 2021 20:03:46
	(b) (4)	

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

US3112128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:12:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:20:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:03:09
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 20:03:46

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:12:21**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User entered '0'	System	26 Feb 2021 20:03:46

**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:12:21**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18
User entered '1'	System	26 Feb 2021 20:03:46



**US3112128**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:12:21**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:39:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:12:21

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 00:08:41
User closed query 'Per CDM: Per Diary Dose 1, subject took medication to treat pain or fever on 12Aug20 and 13Aug20. Please ensure ConMed eCRF is updated accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:02:02
Query 'Per CDM: Per Diary Dose 1, subject took medication to treat pain or fever on 12Aug20 and 13Aug20. Please ensure ConMed eCRF is updated accordingly.' answered with 'Medication not taken for solicited event, rather for the reported AE.' (Site from DM).	Matthew Musikanth (b) (4)	27 Oct 2020 21:24:38
User opened query 'Per CDM: Per Diary Dose 1, subject took medication to treat pain or fever on 12Aug20 and 13Aug20. Please ensure ConMed eCRF is updated accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 12:56:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 01:23:25

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DEGLUDEC, PRODUCTSYNONYM: TRESIBA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:51:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:51:22
Data point term sent to Coder User entered 'Tresiba'	System (b) (4), (b) (6)	20 Aug 2020 15:50:24 20 Aug 2020 15:50:09

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:50:09

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User entered 'Type 1 Diabetes'	(b) (4), (b) (6)	20 Aug 2020 15:50:09

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User entered '32'	(b) (4), (b) (6)	20 Aug 2020 15:50:09

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User entered 'Other (OTHER)'	(b) (4), (b) (6)	20 Aug 2020 15:50:09

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:12:21**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User entered 'Units'	(b) (4), (b) (6)	20 Aug 2020 15:50:09



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 15:50:09

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:50:09

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	20 Aug 2020 15:50:09

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:50:09

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:35:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:50:09
User entered 'UN UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 15:50:09

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:50:09

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:50:09

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:50:09



US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:09
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:50:09

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:50:09

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:50:09

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 15:50:09

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:52:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:52:21
Data point term sent to Coder User entered 'Humalog'	System (b) (4), (b) (6)	20 Aug 2020 15:51:26 20 Aug 2020 15:51:05

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:51:05

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:17:22
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	22 Sep 2020 18:55:12
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:32:32
User entered 'Type 1 Diabetes'	(b) (4), (b) (6)	20 Aug 2020 15:51:05

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User entered '12-30'	(b) (4), (b) (6)	20 Aug 2020 15:51:05



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User entered 'Other (OTHER)'	(b) (4), (b) (6)	20 Aug 2020 15:51:05

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User entered 'Units'	(b) (4), (b) (6)	20 Aug 2020 15:51:05

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User entered 'other (OTHER)'	(b) (4), (b) (6)	20 Aug 2020 15:51:05

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User entered 'Every meal'	(b) (4), (b) (6)	20 Aug 2020 15:51:05

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	20 Aug 2020 15:51:05

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:51:05

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:35:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:51:05
User entered 'UN UNK 2002'	(b) (4), (b) (6)	20 Aug 2020 15:51:05

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:51:05



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:51:05

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:51:05

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:12:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:25:33
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:51:05

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:12:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 15:51:05

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 15:51:05

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 15:51:05

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: DIFLUPREDNATE, PRODUCTSYNONYM: DUREZOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 22:44:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 22:44:39
Data point term sent to Coder	System	22 Sep 2020 18:57:58
Coding entries removed.	Matthew Musikanth (b) (4)	22 Sep 2020 18:57:24
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: DIFLUPREDNATE, PRODUCTSYNONYM: DUREZOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 09:59:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 09:59:12
Data point term sent to Coder	System	20 Aug 2020 15:59:54
User entered 'Durezol Ophthalmic Drop'	(b) (4), (b) (6)	20 Aug 2020 15:59:52

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:59:52



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). Query 'Per DM CLR: Please review the indication to include the specific location of CONJUNCTIVITIS ALLERGIC (i.e. Left, Right, Bilateral). Reconcile and update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:17:51
User entered 'Bilateral CONJUNCTIVITIS ALLERGIC' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	22 Sep 2020 18:57:24
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	22 Sep 2020 18:55:28
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:34:09
User opened query 'Per DM CLR: Please review the indication to include the specific location of CONJUNCTIVITIS ALLERGIC (i.e. Left, Right, Bilateral). Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:33:43
User entered 'Conjunctivitis Allergic'	(b) (4), (b) (6)	20 Aug 2020 15:59:52

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User entered 'l'	(b) (4), (b) (6)	20 Aug 2020 15:59:52

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User entered 'Other (OTHER)'	(b) (4), (b) (6)	20 Aug 2020 15:59:52

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User entered 'Application'	(b) (4), (b) (6)	20 Aug 2020 15:59:52

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	20 Aug 2020 15:59:52

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:59:52

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	20 Aug 2020 15:59:52

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:59:52



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User entered 'UN Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 15:59:52

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:59:52

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 18:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:59:52

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User closed query 'Ongoing is Yes, however End dateSystem is provided. Please correct.' (Site from System).		21 Aug 2020 18:06:53
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	20 Aug 2020 15:59:52
User entered '07 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 15:59:52

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:28:31
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:59:52

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:12:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User entered empty.	System	20 Aug 2020 15:59:52

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User entered empty.	System	20 Aug 2020 15:59:52

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:31
User entered empty.	System	20 Aug 2020 15:59:52



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: MYDRIATICS AND CYCLOPLEGICS, ATC: ANTICHOLINERGICS, PRODUCT: CYCLOPENTOLATE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 10:20:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 10:20:59
Data point term sent to Coder	System	22 Sep 2020 18:57:58
Coding entries removed.	Matthew Musikanth (b) (4)	22 Sep 2020 18:57:11
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: MYDRIATICS AND CYCLOPLEGICS, ATC: ANTICHOLINERGICS, PRODUCT: CYCLOPENTOLATE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 09:52:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 09:52:09
Data point term sent to Coder	System	20 Aug 2020 16:01:57
User entered 'Cyclopentolate Hydrochloride'	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User closed query 'Per DM CLR: Please review the indication to include the specific location of CONJUNCTIVITIS ALLERGIES (i.e. Left, Right, Bilateral). Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:18:02
Query 'Per DM CLR: Please review the indication to include the specific location of CONJUNCTIVITIS ALLERGIES (i.e. Left, Right, Bilateral). Reconcile and update as appropriate.' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	22 Sep 2020 18:57:16
User entered 'Bilateral CONJUNCTIVITIS ALLERGIES' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	22 Sep 2020 18:57:11
User opened query 'Per DM CLR: Please review the indication to include the specific location of CONJUNCTIVITIS ALLERGIES (i.e. Left, Right, Bilateral). Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:34:56
User entered 'Conjunctivitis Allergies'	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User entered 'I'	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User entered 'Other (OTHER)'	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User entered 'Application'	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:01:31



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User entered 'UN Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 18:07:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 18:07:16
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:29:20
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 16:01:31

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:12:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User entered empty.	System	20 Aug 2020 16:01:31



US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User entered empty.	System	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:35
User entered empty.	System	20 Aug 2020 16:01:31

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: NORETHISTERONE, PRODUCTSYNONYM: ERRIN [NORETHISTERONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:03:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:03:24
Data point term sent to Coder User entered 'Errin'	System (b) (4), (b) (6)	20 Aug 2020 16:02:59 20 Aug 2020 16:02:32

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 16:02:32

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User entered 'Birth Control'	(b) (4), (b) (6)	20 Aug 2020 16:02:32

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User entered '0.35' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 18:05:51
User entered 'UN'	(b) (4), (b) (6)	20 Aug 2020 16:02:32

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	21 Aug 2020 18:06:13
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	21 Aug 2020 18:05:51
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 18:05:51
User entered 'Other (OTHER)'	(b) (4), (b) (6)	20 Aug 2020 16:02:32

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 18:06:13
User entered 'UNK'	(b) (4), (b) (6)	20 Aug 2020 16:02:32



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 18:05:51
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	20 Aug 2020 16:02:32

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:02:32

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 16:02:32

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:02:32

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:35:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:02:32
User entered 'UN May 2020'	(b) (4), (b) (6)	20 Aug 2020 16:02:32

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 16:02:32

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:02:32

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:02:32



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:30:27
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 16:02:32

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:12:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:05:51
User entered empty.	System	20 Aug 2020 16:02:32

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:05:51
User entered empty.	System	20 Aug 2020 16:02:32

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 18:05:51
User entered empty.	System	20 Aug 2020 16:02:32

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:15:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:15:06
Data point term sent to Coder	System	27 Oct 2020 21:26:32
User entered 'Morphine'	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User entered 'RLQ Pain'	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 21:26:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 21:26:57
User entered 'UNK' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	27 Oct 2020 21:26:57
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 21:25:37
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 14:02:29
Query 'Data is required. Please complete.' answered with 'Information unknown, patient unable to report and medical records nondescript. ' (Site from System).	Matthew Musikanth (b) (4)	27 Oct 2020 21:27:08
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 21:25:37
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User entered 'as needed (PRN)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	27 Oct 2020 21:27:44
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	27 Oct 2020 21:26:57
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	27 Oct 2020 21:26:57
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	27 Oct 2020 21:25:37
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM). Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'AE date has been updated ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 18:41:12
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 23:21:57
User entered '12 Aug 2020'	(b) (4), (b) (6)	10 Jan 2021 12:08:35
	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User entered '13 Aug 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	27 Oct 2020 21:27:44
User entered '12 Aug 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	27 Oct 2020 21:26:57
User entered '13 Aug 2020'	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:35:53
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 21:27:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 21:27:02
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	27 Oct 2020 21:27:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 21:25:37
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:25:37

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:12:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User entered empty.	System	27 Oct 2020 21:25:37

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User entered empty.	System	27 Oct 2020 21:25:37

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:45
User entered empty.	System	27 Oct 2020 21:25:37

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 05:48:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 05:48:13
Data point term sent to Coder	System	21 Jan 2021 17:32:33
Coding entries removed.	Matthew Musikanth (b) (4)	21 Jan 2021 17:32:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:23:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:23:54
Data point term sent to Coder	System	27 Oct 2020 21:29:35
User entered 'Rocephin IV'	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User entered 'UTI' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Jan 2021 17:32:20
User entered 'RLQ Pain'	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User entered 'UNK'	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 14:02:36
Query 'Data is required. Please complete.' answered with 'Information unknown, patient unable to report and medical records nondescript. ' (Site from System).	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:59
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 21:28:55
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM). Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'AE date has been updated ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 18:41:29
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 23:22:09
User entered '12 Aug 2020'	(b) (4), (b) (6)	10 Jan 2021 12:09:24
	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User entered '12 Aug 2020'	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:23
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:28:55

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:12:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User entered empty.	System	27 Oct 2020 21:28:55

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User entered empty.	System	27 Oct 2020 21:28:55

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:22
User entered empty.	System	27 Oct 2020 21:28:55



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 18:58:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 18:58:11
Data point term sent to Coder	System	21 Jan 2021 17:34:38
Coding entries removed.	Matthew Musikanth	21 Jan 2021 17:34:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Oct 2020 22:13:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:13:35
Data point term sent to Coder	System	27 Oct 2020 21:30:38
User entered 'Doxycycline'	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Jan 2021 17:34:19
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User entered 'PREVENTATIVE FOR Potential PID (PER MEDICAL RECORDS)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Jan 2021 17:34:31
User entered 'Preventative for PID (Per Medical records)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Jan 2021 17:34:19
User entered 'RLQ pain'	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User entered 'UNK'	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 14:02:42
Query 'Data is required. Please complete.' answered with 'Information unknown, patient unable to report and medical records nondescript. ' (Site from System).	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:39
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 21:30:34
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User entered 'unknown (UNKNOWN)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 18:41:41
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'AE date has been updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 23:22:21
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 12:09:53
User entered '12 Aug 2020'	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	13 Nov 2020 21:44:36
User entered '26 Aug 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	13 Nov 2020 21:44:36
Comment added 'Information unknown, patient unable to report and medical records nondescript.'	Matthew Musikanth (b) (4)	27 Oct 2020 21:37:37
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	27 Oct 2020 21:31:01
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	27 Oct 2020 21:31:01
User entered 'UN Aug 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	27 Oct 2020 21:31:01
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	27 Oct 2020 21:30:51
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	27 Oct 2020 21:30:51
User entered 'un UNK 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:51
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	27 Oct 2020 21:30:34
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:23
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User entered empty.	System	27 Oct 2020 21:30:34



US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User entered empty.	System	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:17
User entered empty.	System	27 Oct 2020 21:30:34

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: CEFTIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 17:34:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 17:34:03
Data point term sent to Coder	System	21 Jan 2021 17:33:35
Coding entries removed.	Matthew Musikanth (b) (4)	21 Jan 2021 17:32:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: CEFTIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 21:40:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 21:40:30
Data point term sent to Coder	System	27 Oct 2020 21:38:45
User entered 'Ceftin'	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User entered 'UTI' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Jan 2021 17:32:38
User entered 'RLQ Pain'	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User entered 'unk'	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 14:02:49
Query 'Data is required. Please complete.' answered with 'Information unknown, patient unable to report and medical records nondescript. ' (Site from System).	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:22
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 21:38:18
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User entered 'unknown (UNKNOWN)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 18:41:59
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'AE date has been updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 23:22:32
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 12:10:14
User entered '12 Aug 2020'	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	13 Nov 2020 21:44:23
User entered '22 Aug 2020' reason for change: New Information	Matthew Musikanth (b) (4)	13 Nov 2020 21:44:23
Comment added 'Information unknown, patient unable to report and medical records nondescript.'	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:28
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	27 Oct 2020 21:38:18
User entered 'un Aug 2020'	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:37:48
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:38:18

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:12:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User entered empty.	System	27 Oct 2020 21:38:18

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User entered empty.	System	27 Oct 2020 21:38:18

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:29
User entered empty.	System	27 Oct 2020 21:38:18

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 18:19:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 18:19:05
Data point term sent to Coder	System	21 Jan 2021 16:49:44
User entered 'Ceftriaxone'	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered 'UTI Leukocytosis'	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered '2'	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered 'g (g)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered 'q24H'	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth	21 Jan 2021 16:49:24
	(b) (4)	

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered '22 Nov 2020'	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered '24 Nov 2020'	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:35
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User entered empty.	System	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User entered empty.	System	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:12:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:02
User entered empty.	System	21 Jan 2021 16:49:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 16:51:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 16:51:05
Data point term sent to Coder	System	21 Jan 2021 16:50:45
User entered 'Fluconazole'	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered 'Vaginal Candidiasis'	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered '200'	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered '23 Nov 2020'	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered '27 Nov 2020'	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:38:56
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User entered '1'	System	21 Jan 2021 16:50:24

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User entered '1'	System	21 Jan 2021 16:50:24

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:12:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:06
User entered '804 (804)'	System	21 Jan 2021 16:50:24



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:36:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:36:01
Data point term sent to Coder	System	05 Mar 2021 16:35:08
Coding entries removed.	Matthew Musikanth (b) (4)	05 Mar 2021 16:34:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 05:54:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 05:54:13
Data point term sent to Coder	System	21 Jan 2021 16:52:48
User entered 'Wellbutrin'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User closed query 'Per DM CLR: Please review the indication and provide the medical condition that this medication was used to prevent/treat, rather than the action of the medication. Please update the indication as appropriate and ensure to update MH/Adverse event eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 02:13:55
Query 'Per DM CLR: Please review the indication and provide the medical condition that this medication was used to prevent/treat, rather than the action of the medication. Please update the indication as appropriate and ensure to update MH/Adverse event eCRF as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	05 Mar 2021 16:34:32
User entered 'Bipolar Disorder' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:34:22
User opened query 'Per DM CLR: Please review the indication and provide the medical condition that this medication was used to prevent/treat, rather than the action of the medication. Please update the indication as appropriate and ensure to update MH/Adverse event eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:37:29
User entered 'Antidepressant'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User entered '150'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User entered 'un UNK 2018'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User entered '22 Nov 2020'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:00
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User entered '1'	System	21 Jan 2021 16:52:29



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User entered '1'	System	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:12:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:00:10
User entered '804 (804)'	System	21 Jan 2021 16:52:29

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:36:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:36:01
Data point term sent to Coder Coding entries removed.	System Matthew Musikanth (b) (4)	05 Mar 2021 16:35:10 05 Mar 2021 16:34:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 05:54:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 05:54:14
Data point term sent to Coder User entered 'Wellbutrin'	System Matthew Musikanth (b) (4)	21 Jan 2021 16:53:49 21 Jan 2021 16:52:56

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User closed query 'Per DM CLR: Please review the indication and provide the medical condition that this medication was used to prevent/treat, rather than the action of the medication. Please update the indication as appropriate and ensure to update MH/Adverse event eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 02:14:08
Query 'Per DM CLR: Please review the indication and provide the medical condition that this medication was used to prevent/treat, rather than the action of the medication. Please update the indication as appropriate and ensure to update MH/Adverse event eCRF as appropriate. Otherwise, clarify.' answered with 'Updated to reflect indication of Bipolar Disorder (Manic Depression)' (Site from DM).	Matthew Musikanth (b) (4)	05 Mar 2021 16:35:03
User entered 'Bipolar Disorder' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:34:48
User opened query 'Per DM CLR: Please review the indication and provide the medical condition that this medication was used to prevent/treat, rather than the action of the medication. Please update the indication as appropriate and ensure to update MH/Adverse event eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:38:09
User entered 'Antidepressant'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User entered '200'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User entered '23 Nov 2020'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:40:45
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 16:53:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 16:53:07
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Jan 2021 16:53:07
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 16:52:56
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:52:56

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:12:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 16:52:56

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 16:52:56

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Jan 2021 16:52:56

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: LITHIUM, PRODUCT: LITHIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 17:13:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 17:13:03
Data point term sent to Coder	System	21 Jan 2021 16:57:53
User entered 'Lithium'	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 16:58:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 16:58:00
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Jan 2021 16:58:00
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 16:57:51
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User entered 'Bipolar Disorder'	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User entered '300'	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User entered 'un UNK 2018'	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:07
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 16:58:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 16:58:00
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Jan 2021 16:58:00
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 16:57:51
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 16:57:51

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:12:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 16:57:51

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 16:57:51

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 16:57:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening DIABETES; or if this refers to AE#4 DIABETIC KETOACIDOSIS, please reconcile event terms so there is an appropriate match. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 02:16:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:27:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:27:53
Data point term sent to Coder	System	05 Mar 2021 16:26:55
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening DIABETES; or if this refers to AE#4 DIABETIC KETOACIDOSIS, please reconcile event terms so there is an appropriate match. Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	05 Mar 2021 16:26:03
Coding entries removed.	Matthew Musikanth (b) (4)	05 Mar 2021 16:25:58

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

Name of Medication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening DIABETES; or if this refers to AE#4 DIABETIC KETOACIDOSIS, please reconcile event terms so there is an appropriate match. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:46:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 17:04:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 17:04:11
Data point term sent to Coder	System	21 Jan 2021 17:02:57
User entered 'Lantus'	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered 'DIABETIC KETOACIDOSIS' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Mar 2021 16:25:58
User entered 'Diabetes'	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered '32'	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered 'units'	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered '22 Nov 2020'	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered '23 Nov 2020'	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:38
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 17:02:51

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:12:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User entered '2'	System	21 Jan 2021 17:02:51

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User entered '1'	System	21 Jan 2021 17:02:51



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:12:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:40
User entered '804 (804)'	System	21 Jan 2021 17:02:51

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 00:57:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 00:57:26
Data point term sent to Coder	System	21 Jan 2021 17:05:07
User entered 'Keflex'	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered 'UTI leukocytosis'	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered '250'	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered 'four times daily (QID)'	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered empty.	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered '24 Nov 2020'	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered '0'	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered '01 Dec 2020'	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:43:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Jan 2021 17:04:55



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User entered '4'	System	21 Jan 2021 17:04:55

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User entered '1'	System	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:12:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:46
User entered '804 (804)'	System	21 Jan 2021 17:04:55

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 17:45:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 17:45:07
Data point term sent to Coder	System	26 Feb 2021 17:44:29
User entered 'Flu Vaccine'	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered 'Flu Prophylaxis'	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered '.5'	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered 'mL (mL)'	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered 'Intramuscular (INTRAMUSCULAR)'	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered '16 Oct 2020'	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered '16 Oct 2020'	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:41
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:12:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User entered empty.	System	26 Feb 2021 17:44:04

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User entered empty.	System	26 Feb 2021 17:44:04

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:30
User entered empty.	System	26 Feb 2021 17:44:04

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 20:08:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 20:08:53
Data point term sent to Coder	System	26 Feb 2021 20:08:07
User entered 'Ibuprofen'	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered 'Viral Syndrome'	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered '800'	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered '25 Oct 2020'	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47



US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered '25 Oct 2020'	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47

US3112128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:12:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:34:36
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 20:07:47

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:12:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User entered empty.	System	26 Feb 2021 20:07:47

**US3112128**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User entered empty.	System	26 Feb 2021 20:07:47

US3112128

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:12:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:59:34
User entered empty.	System	26 Feb 2021 20:07:47

US3112128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:12:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:50:54
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	15 Mar 2021 20:50:33
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 23:14:52



US3112128

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:12:21

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:00:51
User entered '18 Sep 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 23:03:03

US3112128

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:12:21

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:00:51
User entered 'AE (specify) (ADVERSE EVENT)'	Matthew Musikanth (b) (4)	08 Dec 2020 23:03:03

US3112128

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:12:21

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)	29 Apr 2021 06:55:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
User closed query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #2 for row 2). ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:56:12
Query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #2 for row 2). ' answered with 'AE log number has already been added ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	15 Mar 2021 16:51:58
User opened query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #2 for row 2). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:24:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:00:51
User closed query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #2).' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 20:10:25
Query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #2).' answered with 'updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	02 Mar 2021 23:55:55
User entered 'PT. UNABLE TO CONTINUE DUE TO RLQ (AE#2) CONCERNS RELATED TO ONGOING AE, PER PI' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	02 Mar 2021 23:55:43

US3112128

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:12:21

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #2).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:18:04
User closed query 'Per CDM: Please clarify the specific AE that resulted in the subject dosing discontinuation. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:41:29
Query 'Per CDM: Please clarify the specific AE that resulted in the subject dosing discontinuation. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	11 Feb 2021 22:50:01
User entered 'PT. UNABLE TO CONTINUE DUE TO RLQ CONCERNS RELATED TO ONGOING AE, PER PI' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	11 Feb 2021 22:49:57
User opened query 'Per CDM: Please clarify the specific AE that resulted in the subject dosing discontinuation. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 18:13:10
User entered 'Pt. unable to continue due to concerns related to ongoing AE, per PI'	Matthew Musikanth (b) (4)	08 Dec 2020 23:03:03

**US3112128**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:12:21**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'USA-US062-2020-MRNA-1273-P301000011'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Yes (Y)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Yes (Y)'	System	29 Dec 2020 16:56:37
User entered 'No (N)'	System	29 Dec 2020 16:55:47



US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 16:38:55
User entered 'Yes (Y)'	System	21 Jan 2021 16:06:41
Un-reviewed for Safety.	System	12 Jan 2021 18:34:42
User entered 'No (N)'	System	12 Jan 2021 18:34:42
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Yes (Y)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Laurie'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Han-Conrad'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered '9040 Friars Rd St 540'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'San Diego'	System	29 Dec 2020 16:55:47



US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'CA'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered '92108'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:57:07
User entered 'US'	System	29 Dec 2020 16:56:59

**US3112128**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:12:21**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Jan 2021 16:42:51
User entered '2'	System	22 Jan 2021 16:39:12
User entered '1'	System	29 Dec 2020 16:56:59

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'USA-US062-2020-MRNA-1273-P301000011'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Yes (Y)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Yes (Y)'	System	29 Dec 2020 16:56:37
User entered 'No (N)'	System	29 Dec 2020 16:55:47



US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 16:38:55
User entered 'Yes (Y)'	System	21 Jan 2021 16:06:41
Un-reviewed for Safety.	System	12 Jan 2021 18:34:42
User entered 'No (N)'	System	12 Jan 2021 18:34:42
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Yes (Y)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Laurie'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Han-Conrad'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered '9040 Friars Rd St 540'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'San Diego'	System	29 Dec 2020 16:55:47



US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'CA'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered '92108'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:57:07
User entered 'US'	System	29 Dec 2020 16:56:59

**US3112128**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:12:21**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Jan 2021 16:42:51
User entered '2'	System	22 Jan 2021 16:39:12
User entered '1'	System	29 Dec 2020 16:56:59

**US3112128**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:12:21**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
User entered '29/Dec/2020 11:56'	System	29 Dec 2020 16:56:59

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:12:21

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:57:07
User entered 'I'	(b) (4), (b) (6)	29 Dec 2020 16:56:59

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'USA-US062-2020-MRNA-1273-P301000011'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Yes (Y)'	System	29 Dec 2020 16:55:47



US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Yes (Y)'	System	29 Dec 2020 16:56:37
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 16:38:55
User entered 'Yes (Y)'	System	21 Jan 2021 16:06:41
Un-reviewed for Safety.	System	12 Jan 2021 18:34:42
User entered 'No (N)'	System	12 Jan 2021 18:34:42
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Yes (Y)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Laurie'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Han-Conrad'	System	29 Dec 2020 16:55:47



US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered '9040 Friars Rd St 540'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'San Diego'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'CA'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered '92108'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:57:07
User entered 'US'	System	29 Dec 2020 16:56:59

**US3112128**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:12:21**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Jan 2021 16:42:51
User entered '2'	System	22 Jan 2021 16:39:12
User entered '1'	System	29 Dec 2020 16:56:59

**US3112128**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:12:21**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
User entered '22/Jan/2021 11:39'	System	22 Jan 2021 16:39:12

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:12:21

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 16:42:34
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 16:39:12



US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'USA-US062-2020-MRNA-1273-P301000011'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Yes (Y)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Yes (Y)'	System	29 Dec 2020 16:56:37
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 16:38:55
User entered 'Yes (Y)'	System	21 Jan 2021 16:06:41
Un-reviewed for Safety.	System	12 Jan 2021 18:34:42
User entered 'No (N)'	System	12 Jan 2021 18:34:42
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Yes (Y)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'No (N)'	System	29 Dec 2020 16:55:47



US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Laurie'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'Han-Conrad'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered '9040 Friars Rd St 540'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'San Diego'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered 'CA'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:52
User entered '92108'	System	29 Dec 2020 16:55:47

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:57:07
User entered 'US'	System	29 Dec 2020 16:56:59

**US3112128**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:12:21**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Jan 2021 16:42:51
User entered '2'	System	22 Jan 2021 16:39:12
User entered '1'	System	29 Dec 2020 16:56:59



**US3112128**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:12:21**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
User entered '22/Jan/2021 11:42'	System	22 Jan 2021 16:42:51

US3112128

Folder: SAE USA-US062-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:12:21

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:39:09
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 16:42:51