

US3292320 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:33:11

All time stamps listed in this document are displayed in GMT

US3292320

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

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[Participant ID](#)

US3292320

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

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US3292320

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3292320

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	54
Age Units	YEARS
Age (Derived)	54
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	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) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Date of Informed Consent ( <i>dd MMM yyyy</i> )	25 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

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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) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

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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) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Condition	LEFT TOE SURGERY
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Condition	INJURY TO LEFT BIG TOE
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Condition	ADHESIVE ALLERGY
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Condition	LOW BACK PAIN
Start date (dd MMM yyyy)	UN UNK 1991
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 1991
Start Year (derived)	1991
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Condition	COLONIC POLYP
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Condition	R SHOULDER JOINT PAIN
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	15:16 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 15:16
Height (xxx.x)	175.5 cm
Weight (xxx.x)	95.6 kg
BMI (xxx.x)	31.03871 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

25 AUG 2020

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*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: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

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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** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 14:14:15

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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)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

What was the date of randomization? (dd MMM yyyy) 25 AUG 2020

What was the participant's randomization number? 108491

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☒   
 >=18 and <65 years and at risk ☐   
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

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) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

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)	25 AUG 2020
Time of assessment (00:00-23:59)	15:22 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 15:22
Temperature (xxx.x)	036.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	075 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	089 mmHg
Diastolic Blood Pressure units	MMHG

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	17:06 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 17:06
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 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)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

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: Exposure

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

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) 25 AUG 2020

What was the treatment time? (00:00-23:59) 16:31 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 16:31

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) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 AUG 2020

Collection time (00:00-23:59)

15:29 (24 HR)

Collection date and time (derived)

25 AUG 2020 15:29

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:45	25 AUG 2020 15:45
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

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 16:33:11

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

25 AUG 2020 17:09

PC Open Date & Time

25 AUG 2020 16:51

PC Close Date & Time

25 AUG 2020 19:21

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 25 AUG 2020 21:31

PC Open Date & Time 25 AUG 2020 20:16

PC Close Date & Time 26 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 00:06

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 02:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 00:33

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 22:30

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 13:14

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59



US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**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):

PC Time Stamp

31 AUG 2020 22:41

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 17:07

PC Open Date & Time

25 AUG 2020 16:51

PC Close Date & Time

25 AUG 2020 19:21

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**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

25 AUG 2020 21:32

PC Open Date & Time

25 AUG 2020 20:16

PC Close Date & Time

26 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**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

27 AUG 2020 00:06

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**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

28 AUG 2020 02:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**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

29 AUG 2020 00:33

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**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

29 AUG 2020 22:30

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**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

30 AUG 2020 13:14

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59



US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**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

31 AUG 2020 22:42

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**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 ☐

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 17:10
PC Open Date & Time	25 AUG 2020 16:51
PC Close Date & Time	25 AUG 2020 19:21

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**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 ☐

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 21:32
PC Open Date & Time	25 AUG 2020 20:16
PC Close Date & Time	26 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

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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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 00:07
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

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 ☒

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EAB) (1725)



US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 02:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**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 ☒

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EAB) (1725)

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 00:34
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 22:31
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

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)

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 13:14
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 22:42
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3292320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

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

CONTACT NOT MADE DUE TO  
ERROR

If Contact Not Made, please provide Comments

US3292320

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292320

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292320

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2



US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

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 SEP 2020
Time of assessment (00:00-23:59)	14:17 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 14:17
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 16:00
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3292320

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 15:30 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 15:30

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

US3292320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 SEP 2020
Collection time (00:00-23:59)	14:25 (24 HR)
Collection date and time (derived)	22 SEP 2020 14:25

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:42	22 SEP 2020 14:42
Nasopharyngeal Swab 2	No		

US3292320

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 16:02

PC Open Date & Time

22 SEP 2020 15:50

PC Close Date & Time

22 SEP 2020 18:20



US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °F

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

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

PC Time Stamp	23 SEP 2020 03:37
PC Open Date & Time	22 SEP 2020 19:15
PC Close Date & Time	23 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**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

97.1 °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

23 SEP 2020 19:29

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 02:38

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**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

25 SEP 2020 20:46

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 23:10

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 00:43

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 23:37

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 16:03

PC Open Date & Time

22 SEP 2020 15:50

PC Close Date & Time

22 SEP 2020 18:20



US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**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

23 SEP 2020 03:38

PC Open Date & Time

22 SEP 2020 19:15

PC Close Date & Time

23 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**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

23 SEP 2020 19:29

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**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

25 SEP 2020 02:38

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**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

25 SEP 2020 20:46

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**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

26 SEP 2020 23:11

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**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

28 SEP 2020 00:43

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**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

28 SEP 2020 23:37

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**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 ☐



US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 16:03
PC Open Date & Time	22 SEP 2020 15:50
PC Close Date & Time	22 SEP 2020 18:20

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**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 ☐

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 03:38
PC Open Date & Time	22 SEP 2020 19:15
PC Close Date & Time	23 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

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)

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 19:30
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 02:38
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 20:47
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

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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EAB) (1725)

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 23:11
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

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

EAB) (1725)

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US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 00:43
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

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 ☒

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US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 23:38
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3292320

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments 3 ATTEMPTS MADE TO  
SUBJECT, CALL WENT  
STRAIGHT TO VOICEMAIL,  
VOICEMAIL BOX FULL UNABLE  
TO LVM.

*If Contact Not Made, please provide Comments*



US3292320

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292320

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292320

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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	VISIT3

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 10:50
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292320

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

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.*



US3292320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 OCT 2020
Collection time (00:00-23:59)	11:07 (24 HR)
Collection date and time (derived)	21 OCT 2020 11:07

US3292320

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:14:15

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 09:29:15

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 NOV 2020 04:15:25

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 10:11:45

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

<b>TIMEPOINT</b>	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 00:20:49
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 00:07:22
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 00:01:54

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59



US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 20:52:49
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 00:02:10

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 01:59:04
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 12:05:27

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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

Date and time of submission

10 JAN 2021 02:15:22

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 JAN 2021 06:55:12
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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

Date and time of submission

21 JAN 2021 00:16:17

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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

Date and time of submission

01 FEB 2021 21:51:03

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59



US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 12:02:39
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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

11 FEB 2021 00:03:38

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 00:54:17
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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

26 FEB 2021 06:31:45

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 13:01:54
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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

11 MAR 2021 04:03:40

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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

Date and time of submission

18 MAR 2021 15:09:35

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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

Date and time of submission

26 MAR 2021 10:40:43

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59



US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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

Date and time of submission

03 APR 2021 12:00:24

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 12:05:40

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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

Date and time of submission

15 APR 2021 23:59:56

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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

Date and time of submission

25 APR 2021 13:43:19

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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

Date and time of submission

30 APR 2021 14:34:27

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	08 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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[Patient Cloud Close Date & Time](#)

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20 SEP 2021 23:59

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US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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="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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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="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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	11 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 NOV 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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02 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 DEC 2021 23:59

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US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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09 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2021 23:59

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US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 JAN 2022 00:01

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10 JAN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 JAN 2022 00:01

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17 JAN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 JAN 2022 00:01

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24 JAN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

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31 JAN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 FEB 2022 00:01

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07 FEB 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

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21 FEB 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 FEB 2022 00:01

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28 FEB 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 MAR 2022 00:01

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07 MAR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 MAR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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°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 ☐



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 MAR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 MAR 2022 00:01

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28 MAR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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°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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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="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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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="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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 JUN 2022 00:01

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20 JUN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 JUN 2022 00:01

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27 JUN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 JUN 2022 00:01

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04 JUL 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 JUL 2022 00:01

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11 JUL 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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="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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

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14 JUL 2022 00:01

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18 JUL 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

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25 JUL 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

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28 JUL 2022 00:01

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01 AUG 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>



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**Folder: New 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.

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

Date and time of submission

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04 AUG 2022 00:01

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08 AUG 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

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11 AUG 2022 00:01

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15 AUG 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

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05 SEP 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

Date and time of submission

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08 SEP 2022 00:01

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12 SEP 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

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15 SEP 2022 00:01

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19 SEP 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	06 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**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 ☐

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

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 <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"/>



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3292320

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:33:11

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
No		01 MAR 2021 03:45:50

US3292320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292320

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292320

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292320

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292320

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292320

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:41:59

Generated On: 09 Jun 2021 16:33:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3292320

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:41:59

Generated On: 09 Jun 2021 16:33:11

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) \_\_\_\_\_

US3292320

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:41:59

Generated On: 09 Jun 2021 16:33:11

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.*

US3292320

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:41:59

Generated On: 09 Jun 2021 16:33:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 APR 2021

Collection time (00:00-23:59)

10:42 (24 HR)

Collection date and time (derived)

6 APR 2021 10:42

US3292320

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:41:59

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 18:35:04

Generated On: 09 Jun 2021 16:33:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3292320

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 18:35:04

Generated On: 09 Jun 2021 16:33:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3292320**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

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*

**US3292320**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 14:14:10

Generated On: 09 Jun 2021 16:33:11

Date of Contact	17 NOV 2020
Time of Contact	16:04
Date and Time of Contact (derived)	17 NOV 2020 16:04
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" 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>

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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"/>

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input 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 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"/>

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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"/>



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Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input 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 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 17 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 17 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input 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 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 17 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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"/>



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Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	37.2 C
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 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 17 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	37.5 C
-------------	--------

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"/>

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EAB) (1725)

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input 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 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 17 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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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Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.8 C
-------------	--------

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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input 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 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 17 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	21 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.2 C
-------------	--------

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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 checked="" 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 17 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



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Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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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Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	22 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	35.4 C
-------------	--------

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"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 checked="" 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 17 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 type="checkbox"/>
Day 9	<input checked="" 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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Form: Symptom Log (9)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	23 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.0 C
-------------	--------

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"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (10)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" 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 17 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	24 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.6 C
-------------	--------

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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 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 17 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" 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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Form: Symptom Log (11)

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Generated On: 09 Jun 2021 16:33:11

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	35.6 C
-------------	--------

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"/>

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	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 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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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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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 type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" 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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Form: Symptom Log (12)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.2 C
-------------	--------

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"/>

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	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 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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Form: Symptom Log (12)

Data signed: (b) (4) 22 Apr 2021 15:51:35

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (13)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" 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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Form: Symptom Log (13)

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	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	35.5 C
-------------	--------

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"/>

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Form: Symptom Log (13)

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	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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Form: Symptom Log (13)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



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Form: Symptom Log (14)

Data signed: (b) (4) 22 Apr 2021 15:51:35

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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 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 checked="" 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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Form: Symptom Log (14)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.2 C
-------------	--------

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"/>

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	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 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 17 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (15)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" 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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Form: Symptom Log (15)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	29 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.3 C
-------------	--------

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"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" 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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Form: Symptom Log (16)

Data signed: (b) (4) 22 Apr 2021 15:51:35

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	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	30 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.4 C
-------------	--------

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"/>

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Form: Symptom Log (16)

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 17 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (17)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" 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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Form: Symptom Log (17)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	1 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	36.4 C	
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"/>

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	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 17 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



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Form: Symptom Log (18)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" 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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Form: Symptom Log (18)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	2 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.4 C
-------------	--------

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"/>

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Generated On: 09 Jun 2021 16:33:11

	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 17 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (19)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" 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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Form: Symptom Log (19)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	3 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.0 C
-------------	--------

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"/>

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Form: Symptom Log (19)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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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Form: Symptom Log (19)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 17 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" 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 17 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	4 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.2 C
-------------	--------

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"/>

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Form: Symptom Log (20)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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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Form: Symptom Log (20)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 17 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" 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 17 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	5 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.4 C
-------------	--------

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"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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"/>

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



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Form: Symptom Log (22)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" 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 17 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	6 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.2 C
-------------	--------

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"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 17 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" 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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Form: Symptom Log (23)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	7 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	35.9 C
-------------	--------

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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 17 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



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Form: Symptom Log (24)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" 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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Form: Symptom Log (24)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	8 DEC 2020
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (25)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" 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 17 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	9 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.1 C
-------------	--------

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"/>

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Form: Symptom Log (25)

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	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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Form: Symptom Log (25)

Data signed: (b) (4) 22 Apr 2021 15:51:35

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



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Form: Symptom Log (26)

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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 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 checked="" 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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Form: Symptom Log (26)

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	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	10 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.2 C
-------------	--------

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"/>

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	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 17 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (27)

Data signed: (b) (4) 22 Apr 2021 15:51:35

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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 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 checked="" 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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Form: Symptom Log (27)

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Generated On: 09 Jun 2021 16:33:11

	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	11 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.8 C
-------------	--------

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"/>

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	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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Form: Symptom Log (27)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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"/>



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Form: Symptom Log (28)

Data signed: (b) (4) 22 Apr 2021 15:51:35

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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 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 checked="" 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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Form: Symptom Log (28)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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	12 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.4 C
-------------	--------

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"/>

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	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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Form: Symptom Log (28)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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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Form: Symptom Log (29)

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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 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 checked="" type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (29)

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Generated On: 09 Jun 2021 16:33:11

	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 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (29)

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Generated On: 09 Jun 2021 16:33:11

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>



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Form: Symptom Log (30)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	35.5 C
-------------	--------

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"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 17 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

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 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 checked="" type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	37.1 C
-------------	--------

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"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

	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 17 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 14:14:10

Generated On: 09 Jun 2021 16:33:11

Date of Visit	18 NOV 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 checked="" type="radio"/> No <input type="radio"/>
Date of Test	18 NOV 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)	1

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 14:14:11

Generated On: 09 Jun 2021 16:33:11

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

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

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

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

Start Date \_\_\_\_\_

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 14:14:11

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

**Ventilator Support:**

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☒

Start Date

End Date

**Evidence of Shock:**

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

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 14:14:11

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Hepatic Dysfunction? Yes ☐ No ☒

Start Date

Neurologic Dysfunction? Yes ☐ No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐ No ☒

Date of Assessment

Radiographical Evidence Yes ☐ No ☒

Date of Assessment

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

Start Date

End Date

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 14:14:11

Generated On: 09 Jun 2021 16:33:11

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	20 NOV 2020
Day 5	Yes	22 NOV 2020
Day 7	Yes	24 NOV 2020
Day 9	Yes	26 NOV 2020
Day 14	Yes	1 DEC 2020
Day 21	Yes	08 DEC 2020
Day 28	Yes	15 DEC 2020

US3292320

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 NOV 2020
Time of assessment (00:00-23:59)	15:27 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 15:27
Height (xxx.x)	175.3 cm
Weight (xxx.x)	92.5 kg
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

18 NOV 2020

---

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

---

US3292320

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 NOV 2020

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:14:10

Generated On: 09 Jun 2021 16:33:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD28

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:14:10

Generated On: 09 Jun 2021 16:33:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 DEC 2020
Time of assessment (00:00-23:59)	14:56 (24 HR)
Vital Signs Date and Time (derived)	15 DEC 2020 14:56
Height (xxx.x)	175.3 cm
Weight (xxx.x)	92.5 kg
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:14:10

Generated On: 09 Jun 2021 16:33:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 DEC 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: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 23 Feb 2021 14:14:09

Generated On: 09 Jun 2021 16:33:11

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

15 DEC 2020

US3292320

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:08:47

Generated On: 09 Jun 2021 16:33:11

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

Visit date (dd MMM yyyy)	2 MAR 2021
--------------------------	------------

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 15:51:35

Generated On: 09 Jun 2021 16:33:11

Date of updated informed consent ( <i>dd MMM yyyy</i> )	2 MAR 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> )	2 MAR 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	



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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:08:47

Generated On: 09 Jun 2021 16:33:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 MAR 2021
Collection time (00:00-23:59)	11:38 (24 HR)
Collection date and time (derived)	2 MAR 2021 11:38

US3292320

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 17:08:47

Generated On: 09 Jun 2021 16:33:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 MAR 2021
Collection time (00:00 - 23:59)	11:45
Collection Date and Time (derived)	2 MAR 2021 11:45

US3292320

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 14:13:45

Generated On: 09 Jun 2021 16:33:11

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

AEID	USA-US072-2020-MRNA-1273-P30 1000003
Adverse event	LEFT HIP LABRUM TEAR
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)	27 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)	31 DEC 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 checked="" type="radio"/> Grade 4 <input 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	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	4 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

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PATIENT REPORTED TO CLINIC  
ON 22SEP2020 FOR V2. DURING  
HIS VISIT, HE REPORTED TO  
SUB-I AND CRC THAT HE WAS  
ACTUALLY ADMITTED TO THE  
HOSPITAL DUE TO WHAT WAS  
LATER DIAGNOSED AS A RIGHT  
HIP LABRUM TEAR. WILL  
UPDATE THIS POST AS MORE  
INFORMATION IS COLLECTED.

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

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US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

AEID	
Adverse event	LEUKOCYTOSIS
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)	30 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)	4 SEP 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 (2)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____



US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

AEID

Adverse event

URINARY RETENTION

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)

30 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

4 SEP 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 (3)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

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	False
Concomitant Procedure	True
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)	_____

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

AEID	
Adverse event	FORAMINAL STENOSIS L4/L5
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)	30 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)	10 SEP 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 (4)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

AEID

Adverse event

TROCHANTERIC BURSTITIS

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)

30 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

31 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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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

AEID

Adverse event

ILIOTIBIAL BAND 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)

30 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 SEP 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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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____



US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

AEID	USA-US072-2020-MRNA-1273-P30 1000014
Adverse event	POSITIVE SYMPTOMATIC COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	15 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)	7 DEC 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"/>
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Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

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	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	SYMPTOMS STARTED 15-NOV, ILLNESS VISIT OCCURED ON 18-NOV. POSITIVE ALERT ON 23-NOV. PATIENT WITH RECENT TRAVEL OUT OF STATE
Serious Adverse Event Derived (CSA Programming Field Only)	0
PRODUCTION RELEASE (v12.003 EAB) (1725)	
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Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 23 Feb 2021 14:13:43

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Medically Attended AE Derived (CSA Programming Field Only)	1
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Admitted to ICU Derived (CSA Programming Field Only)	
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US3292320

Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

AEID	
Adverse event	COMMON COLD
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)	15 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)	7 DEC 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 (17)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

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 _____	
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)	_____

US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

AEID	
Adverse event	L25 TOOTH INFECTION
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)	19 JAN 2021
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)	4 FEB 2021
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 (18)

Data signed: (b) (4) 23 Feb 2021 14:13:43

Generated On: 09 Jun 2021 16:33:11

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)	_____

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 14:14:09

Generated On: 09 Jun 2021 16:33:11

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

Yes ☒

No ☐

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

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US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication PREVENTATIVE HEART  
HEALTH

Dose per administration 81

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

BIW

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

	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 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)		
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 (2)

Data signed: (b) (4) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

Name of Medication MOTRIN (IBUPROFEN)

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED  
OSTEOARTHRITIS PAIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:51:34

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	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	UNK 2008
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) 22 Apr 2021 15:51:34

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Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

	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)	2	
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 (4)

Data signed: (b) (4) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication SPINAL OSTEOARTHRITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

	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 2008	
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 (5)

Data signed: (b) (4) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

Name of Medication TESTOSTERONE TREATMENT

Prophylaxis Yes ☐  
No ☒

Indication LOW TESTOSTERONE

Dose per administration 100

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

If dose unit is Other, specify MG/ML

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) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

	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)	UN UNK 2008	
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 checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 30

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) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

	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)	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 (7)

Data signed: (b) (4) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication TEAR IN LEFT HIP LABRUIM

Dose per administration 4

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) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

	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)		05 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 10 SEP 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 (8)

Data signed: (b) (4) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

Name of Medication FLEXERIL

Prophylaxis Yes ☐  
No ☒

Indication TEAR IN LEFT HIP LABRIUM

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

	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)		05 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 08 SEP 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) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐  
No ☒

Indication TEAR IN LEFT HIP LABRUM

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

	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)		05 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 08 SEP 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) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☐  
No ☒

Indication L25 TOOTH INFECTION

Dose per administration 125

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 (10)

Data signed: (b) (4) 22 Apr 2021 15:51:34

Generated On: 09 Jun 2021 16:33:11

	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)	19 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 2 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 14:14:09

Generated On: 09 Jun 2021 16:33:11

---

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

Data signed: (b) (4) 22 Apr 2021 15:51:34

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Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 SEP 2020	LUMBAR/HIP MRI	Adverse Event	
30 AUG 2020	CATHETER PLACEMENT	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:33:11

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:33:11

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 ☐



US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

SAEID	USA-US072-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

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Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

SAEID	USA-US072-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/SEP/2020 10:39
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

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

SAEID	USA-US072-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	14/OCT/2020 11:16
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

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

SAEID	USA-US072-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/NOV/2020 09:02
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

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

SAEID	USA-US072-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	06/NOV/2020 13:14
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

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

SAEID	USA-US072-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	04/JAN/2021 14:52
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

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

SAEID	USA-US072-2020-MRNA-1273-P301000014
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

SAEID	USA-US072-2020-MRNA-1273-P301000014
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	24/NOV/2020 13:55
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



US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

SAEID	USA-US072-2020-MRNA-1273-P301000014
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	23/DEC/2020 14:06
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

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 14:14:14

Generated On: 09 Jun 2021 16:33:11

SAEID	USA-US072-2020-MRNA-1273-P301000014
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	05/JAN/2021 16:24
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

US3292320 (Prod: Clinical Trials of Texas, Inc)

**US3292320**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:33:11**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:23:18
User entered 'US3292320'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 20:34:24

US3292320

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:47:28
User entered 'Yes (Y)'		27 Aug 2020 18:49:50

US3292320

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:47:28
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 20:34:25

US3292320

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

[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 09:04:01
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:47:28
User entered 'Clinic (Clinic)'		27 Aug 2020 18:49:50

**US3292320**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'SCRN'	System	27 Aug 2020 18:49:50



US3292320

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:33:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:47:37
User entered (b) (6) 1966'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 20:34:26

**US3292320**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:33:11**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:47:37
User entered '54'		27 Aug 2020 18:49:57

US3292320

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:33:11

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'YEARS'	System	27 Aug 2020 18:49:57

**US3292320**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:33:11**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '54'	System	25 Aug 2020 21:39:31

US3292320

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:33:11

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 12:18:13
DataPoint Verified.		22 Oct 2020 20:47:37
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.'	Dawn Killian (b) (4)	20 Oct 2020 20:32:54
answered with 'CRC updating' (Site from DM).	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:00:28
User entered 'Male (M)'	(b) (4), (b) (6)	27 Aug 2020 18:49:57

US3292320

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:33:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:47:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'		27 Aug 2020 18:49:57

**US3292320**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:33:11**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:47:37
User entered 'l'		27 Aug 2020 18:49:57

**US3292320**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:33:11**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:47:37
User entered '0'		27 Aug 2020 18:49:57



**US3292320**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:33:11**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:47:37
User entered '0'		27 Aug 2020 18:49:57

US3292320

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:33:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:47:37
User entered '0'		27 Aug 2020 18:49:57

**US3292320**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:33:11**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:47:37
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:49:57

**US3292320**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:33:11**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:47:37
User entered '0'		27 Aug 2020 18:49:57

**US3292320**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:33:11**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:47:37
User entered empty.		27 Aug 2020 18:49:57

**US3292320**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:33:11**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:47:37
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:49:57

**US3292320**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:33:11**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:47:37
User entered '0'		27 Aug 2020 18:49:57

US3292320

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:33:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:48:01
User entered '25 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 21:39:31



**US3292320**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Aug 2020'	System	25 Aug 2020 21:39:31

**US3292320**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2020'	System	25 Aug 2020 21:39:31

**US3292320**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:33:11**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:48:01
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	25 Aug 2020 21:39:31

**US3292320**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:48:01
User entered 'Yes (Y)'		25 Aug 2020 21:39:31

**US3292320**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:48:01
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 21:39:31

**US3292320**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:33:11**

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:48:01
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 21:39:31

**US3292320**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:33:11**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:48:01
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 21:39:31

**US3292320**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:33:11**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:48:01
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 20:34:25



US3292320

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:33:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'l'	System	25 Aug 2020 21:39:37

**US3292320**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
DataPoint Verified.		02 Mar 2021 19:36:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 21:39:37

US3292320

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:33:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
DataPoint Verified.	(b) (4)	02 Mar 2021 19:37:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Per hospital discharge summary, subject has adhesive tape allergy. Please confirm and add to MH (or AE log) as appropriate.' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 20:36:18
User closed query 'Per hospital discharge summary dated 04SEP2020, subject was shown to have the following ongoing conditions that were not listed on the Medical History Log: low back pain, colonic polyp, hypogonadism, OSA, shoulder joint pain, constipation, hyperlipidemia, cervical radiculopathy. Please confirm onset dates with subject, and update medical history log (or adverse events log) as necessary.' (Site from CRA).	(b) (4)	19 Jan 2021 20:36:09
Query 'Per hospital discharge summary, subject has adhesive tape allergy. Please confirm and add to MH (or AE log) as appropriate.' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	05 Nov 2020 22:33:15
Query 'Per hospital discharge summary dated 04SEP2020, subject was shown to have the following ongoing conditions that were not listed on the Medical History Log: low back pain, colonic polyp, hypogonadism, OSA, shoulder joint pain, constipation, hyperlipidemia, cervical radiculopathy. Please confirm onset dates with subject, and update medical history log (or adverse events log) as necessary.' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	05 Nov 2020 22:33:09
User opened query 'Per hospital discharge summary, subject has adhesive tape allergy. Please confirm and add to MH (or AE log) as appropriate.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 21:01:48

US3292320

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:33:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User opened query 'Per hospital discharge summary dated 04SEP2020, subject was shown to have the following ongoing conditions that were not listed on the Medical History Log: low back pain, colonic polyp, hypogonadism, OSA, shoulder joint pain, constipation, hyperlipidemia, cervical radiculopathy. Please confirm onset dates with subject, and update medical history log (or adverse events log) as necessary.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 18:50:49
DataPoint Verified.		23 Oct 2020 18:49:56
Query 'Per hospital discharge summary dated 04SEP2020, subject was shown to have the following ongoing conditions that were not listed on the Medical History Log: low back pain colonic polyp hypogonadism OSA shoulder joint pain constipation hyperlipidemia cervical radiculopathy		23 Oct 2020 18:49:54
Please confirm onset dates with subject, and update medical history log or adverse even log as necessary.' canceled (Site from CRA). User opened query 'Per hospital discharge summary dated 04SEP2020, subject was shown to have the following ongoing conditions that were not listed on the Medical History Log: low back pain colonic polyp hypogonadism OSA shoulder joint pain constipation hyperlipidemia cervical radiculopathy  Please confirm onset dates with subject, and update medical history log or adverse even log as necessary.' (Site from CRA). DataPoint Un-verified.		23 Oct 2020 18:49:47
DataPoint Verified.		23 Oct 2020 18:47:37
		23 Oct 2020 18:45:15
		22 Oct 2020 20:49:35

US3292320

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:33:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:50:23

US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:33:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:50:46
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) (b) (4)	27 Aug 2020 19:50:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:50:30
Data point term sent to Coder	System	27 Aug 2020 18:51:27
User entered 'sinus surgery'	(b) (4), (b) (6)	27 Aug 2020 18:50:43

**US3292320**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered 'un UNK 2017'		27 Aug 2020 18:50:43

US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:33:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered '0'		27 Aug 2020 18:50:43



US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:33:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered 'No (N)'		27 Aug 2020 18:50:43

**US3292320**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered 'un UNK 2017'		27 Aug 2020 18:50:43

**US3292320**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:50:46
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:50:43

**US3292320**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2017'	System	27 Aug 2020 18:50:43

US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:33:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2017'	System	27 Aug 2020 18:50:43

**US3292320**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2017'	System	27 Aug 2020 18:50:43

**US3292320**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2017'	System	27 Aug 2020 18:50:43

US3292320

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:33:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Toe operation, LLT: Toe operation - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 20:51:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 20:51:40
Data point term sent to Coder	System	22 Oct 2020 20:50:49
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User closed query 'Per DM CLR: Please specify the location ((bilateral, left, right big toe, etc.) and type of TOE SURGERY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.		08 Oct 2020 14:39:48
' (Site from DM).		
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Toe operation, LLT: Toe operation - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 00:19:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 00:19:39
Data point term sent to Coder	System	23 Sep 2020 15:54:36
Query 'Per DM CLR: Please specify the location ((bilateral, left, right big toe, etc.) and type of TOE SURGERY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Victoria Hernandez (b) (4)	23 Sep 2020 15:53:45
' answered with 'UPDATED' (Site from DM).		
Coding entries removed.	Victoria Hernandez (b) (4)	23 Sep 2020 15:53:41
User entered 'LEFT TOE SURGERY' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	23 Sep 2020 15:53:41



US3292320

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:33:11

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the location ((bilateral, left, right big toe, etc.) and type of TOE SURGERY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 19:04:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Toe operation, LLT: Toe operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 06:39:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 06:39:36
Data point term sent to Coder	System	27 Aug 2020 18:51:29
User entered 'toe surgery'	(b) (4), (b) (6)	27 Aug 2020 18:51:03

**US3292320**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:50:46
User entered 'un UNK 2005'	(b) (4), (b) (6)	27 Aug 2020 18:51:03

**US3292320**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered '0'		27 Aug 2020 18:51:03

**US3292320**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered 'No (N)'		27 Aug 2020 18:51:03

**US3292320**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:50:46
User entered 'un UNK 2005'	(b) (4), (b) (6)	27 Aug 2020 18:51:03

**US3292320**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:50:46
User entered '0'		27 Aug 2020 18:51:03

**US3292320**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2005'	System	27 Aug 2020 18:51:03

**US3292320**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2005'	System	27 Aug 2020 18:51:03



**US3292320**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2005'	System	27 Aug 2020 18:51:03

**US3292320**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2005'	System	27 Aug 2020 18:51:03

US3292320

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:33:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 20:51:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 20:51:40
Data point term sent to Coder	System	22 Oct 2020 20:50:48
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 00:50:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 00:50:14
Data point term sent to Coder	System	27 Aug 2020 18:51:32
User entered 'deviated septun'	(b) (4), (b) (6)	27 Aug 2020 18:51:20

**US3292320**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:50:46
User entered 'un UNK 2017'	(b) (4), (b) (6)	27 Aug 2020 18:51:20

**US3292320**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered '0'		27 Aug 2020 18:51:20

**US3292320**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered 'No (N)'		27 Aug 2020 18:51:20

**US3292320**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered 'un UNK 2017'		27 Aug 2020 18:51:20

**US3292320**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:50:46
User entered '0'		27 Aug 2020 18:51:20



US3292320

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2017'	System	27 Aug 2020 18:51:20

**US3292320**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2017'	System	27 Aug 2020 18:51:20

**US3292320**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2017'	System	27 Aug 2020 18:51:20

**US3292320**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2017'	System	27 Aug 2020 18:51:20

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:33:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 20:51:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 20:51:40
Data point term sent to Coder	System	22 Oct 2020 20:50:50
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:50:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:50:35
Data point term sent to Coder	System	27 Aug 2020 18:52:34
User entered 'hypertension'	(b) (4), (b) (6)	27 Aug 2020 18:52:19

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered 'un UNK 2018'		27 Aug 2020 18:52:19

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:33:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered '0'		27 Aug 2020 18:52:19

**US3292320**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered 'Yes (Y)'		27 Aug 2020 18:52:19



US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered empty.		27 Aug 2020 18:52:19

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:33:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered '0'		27 Aug 2020 18:52:19

**US3292320**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2018'	System	27 Aug 2020 18:52:19

**US3292320**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2018'	System	27 Aug 2020 18:52:19

**US3292320**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	27 Aug 2020 18:52:19

**US3292320**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	27 Aug 2020 18:52:19

US3292320

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:33:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Toe injury - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 20:51:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 20:51:40
Data point term sent to Coder	System	22 Oct 2020 20:50:50
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Toe injury - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 10:00:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 10:00:33
Data point term sent to Coder	System	27 Aug 2020 18:53:35
User entered 'injury to left big toe'	(b) (4), (b) (6)	27 Aug 2020 18:52:37

**US3292320**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:50:46
User entered 'un UNK 2005'		27 Aug 2020 18:52:37



**US3292320**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:50:46
User entered '0'		27 Aug 2020 18:52:37

**US3292320**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered 'No (N)'		27 Aug 2020 18:52:37

**US3292320**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:50:46
User entered 'un UNK 2005'	(b) (4), (b) (6)	27 Aug 2020 18:52:37

**US3292320**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:52:37

**US3292320**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2005'	System	27 Aug 2020 18:52:37

**US3292320**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2005'	System	27 Aug 2020 18:52:37

US3292320

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2005'	System	27 Aug 2020 18:52:37

**US3292320**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2005'	System	27 Aug 2020 18:52:37



US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:33:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
User closed query 'Please consider updating source with "spinal"' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 20:35:35
User closed query 'Per source, start date of condition wa 2008. Please confirm and update eCRF if appropriate.' (Site from CRA).		06 Nov 2020 19:15:24
Query 'Per source, start date of condition wa 2008. Please confirm and update eCRF if appropriate.'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:41:56
answered with 'updated' (Site from CRA).		
Query 'Please consider updating source with "spinal"' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:41:53
User opened query 'Per source, start date of condition wa 2008. Please confirm and update eCRF if appropriate.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 20:52:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Spinal osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:51:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:51:40
User opened query 'Please consider updating source with "spinal"' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 20:51:18
Data point term sent to Coder	System	22 Oct 2020 20:50:50
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User closed query 'Per DM CLR: Please update the condition to include the location of OSTEOARTHRITIS (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.'		08 Oct 2020 14:40:05
(Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Spinal osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:53:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:53:38

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:33:11

Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the condition to include the location of OSTEOARTHRITIS (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM). Data point term sent to Coder Coding entries removed.	Victoria Hernandez (b) (4) (b) (4)	(b) (4) 23 Sep 2020 15:52:40
	System	23 Sep 2020 15:52:31
	Victoria Hernandez (b) (4) (b) (4)	23 Sep 2020 15:52:27
User entered 'SPINAL OSTEOARTHRITIS' reason for change: Data Entry Error	Victoria Hernandez (b) (4) (b) (4)	23 Sep 2020 15:52:27
User opened query 'Per DM CLR: Please update the condition to include the location of OSTEOARTHRITIS (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 19:05:25
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:50:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:50:44
Data point term sent to Coder	System	27 Aug 2020 18:54:37
User entered 'osteoarthritis'	(b) (4), (b) (6)	27 Aug 2020 18:53:46

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:28
DataPoint Un-verified.	Dawn Killian (b) (4)	29 Oct 2020 16:41:48
User entered 'UN UNK 2008' reason for change:	Dawn Killian (b) (4)	29 Oct 2020 16:41:48
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered empty.		27 Aug 2020 18:53:46

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:33:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:30
DataPoint Un-verified.	Dawn Killian (b) (4)	29 Oct 2020 16:41:48
User entered '0' reason for change: Data Entry Error	(b) (4) Dawn Killian (b) (4)	29 Oct 2020 16:41:48
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered '1'		27 Aug 2020 18:53:46

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:33:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:50:46
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 15:52:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 15:52:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Victoria Hernandez (b) (4) (b) (4)	23 Sep 2020 15:52:32
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 18:53:46
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:53:46

**US3292320**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered empty.		27 Aug 2020 18:53:46

**US3292320**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered '0'		27 Aug 2020 18:53:46

**US3292320**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2008'	System	29 Oct 2020 16:41:48
User entered empty.	System	27 Aug 2020 18:53:46



**US3292320**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2008'	System	29 Oct 2020 16:41:48
User entered empty.	System	27 Aug 2020 18:53:46

**US3292320**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	27 Aug 2020 18:53:46

**US3292320**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	27 Aug 2020 18:53:46

US3292320

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:33:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Con Med for Low Testosterone treatment has been removed from eCRF but another treatment for this condition is listed in source. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:16:07
Query 'Con Med for Low Testosterone treatment has been removed from eCRF but another treatment for this condition is listed in source. Please reconcile.' answered with 'Treatment has been reactivated as per source.' (Site from CRA).	Antonio Gutierrez (b) (4)	05 Nov 2020 22:09:41
User opened query 'Con Med for Low Testosterone treatment has been removed from eCRF but another treatment for this condition is listed in source. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 21:01:51
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 20:51:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 20:51:40
Data point term sent to Coder	System	22 Oct 2020 20:50:50
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:50:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:50:45
Data point term sent to Coder	System	27 Aug 2020 18:54:39
User entered 'low testosterone'	(b) (4), (b) (6)	27 Aug 2020 18:54:02

**US3292320**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered 'un UNK 2018'		27 Aug 2020 18:54:02

**US3292320**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered '0'		27 Aug 2020 18:54:02

**US3292320**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:50:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:54:02

**US3292320**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:50:46
User entered empty.		27 Aug 2020 18:54:02



**US3292320**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:50:46
User entered '0'		27 Aug 2020 18:54:02

**US3292320**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2018'	System	27 Aug 2020 18:54:02

**US3292320**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2018'	System	27 Aug 2020 18:54:02

**US3292320**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	27 Aug 2020 18:54:02

**US3292320**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	27 Aug 2020 18:54:02

US3292320

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:33:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:16:42
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis contact, LLT: Adhesive tape allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:28:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:28:27
Data point term sent to Coder	System	05 Nov 2020 22:28:00
User entered 'Adhesive Allergy'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:27:19

**US3292320**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:16:44
User entered 'UN UNK 2005'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:27:19

**US3292320**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:16:45
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:27:19



**US3292320**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:16:47
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:27:19

**US3292320**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:16:49
User entered 'UN UNK 2005'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:27:19

**US3292320**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:16:51
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:27:19

**US3292320**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2005'	System	05 Nov 2020 22:27:19

**US3292320**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2005'	System	05 Nov 2020 22:27:19

**US3292320**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2005'	System	05 Nov 2020 22:27:19

**US3292320**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2005'	System	05 Nov 2020 22:27:19

US3292320

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:33:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:17:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 22:29:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 22:29:31
Data point term sent to Coder	System	05 Nov 2020 22:29:01
User entered 'Low Back Pain'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:28:08



**US3292320**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:17:46
User entered 'UN UNK 1991'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:28:08

**US3292320**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:17:48
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:28:08

**US3292320**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:17:50
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:28:08

**US3292320**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:17:52
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:28:08

**US3292320**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:17:53
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:28:08

**US3292320**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 1991'	System	05 Nov 2020 22:28:08

**US3292320**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '1991'	System	05 Nov 2020 22:28:08

**US3292320**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:28:08



**US3292320**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:28:08

US3292320

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:33:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:18:11
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:44:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:44:30
Data point term sent to Coder	System	05 Nov 2020 22:29:01
User entered 'Colonic Polyp'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:28:34

**US3292320**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:18:13
User entered 'UN UNK 2016'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:28:34

**US3292320**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:18:14
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:28:34

**US3292320**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:18:17
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:28:34

**US3292320**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:18:20
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:28:34

**US3292320**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:18:21
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:28:34

**US3292320**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2016'	System	05 Nov 2020 22:28:34



**US3292320**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2016'	System	05 Nov 2020 22:28:34

**US3292320**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:28:34

**US3292320**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:28:34

US3292320

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:33:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:18:34
User coded data point as SOC: Endocrine disorders, HLGT: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Hypogonadism, LLT: Hypogonadism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:29:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 22:29:30
Data point term sent to Coder	System	05 Nov 2020 22:29:02
User entered 'Hypogonadism'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:29:00

**US3292320**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:18:36
User entered 'un UNK 2018'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:29:00

**US3292320**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:18:37
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:29:00

**US3292320**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:18:39
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:29:00

**US3292320**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:18:42
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:29:00



**US3292320**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:18:45
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:29:00

**US3292320**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2018'	System	05 Nov 2020 22:29:00

**US3292320**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2018'	System	05 Nov 2020 22:29:00

**US3292320**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:29:00

**US3292320**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:29:00

US3292320

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:33:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:18:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 22:31:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 22:31:28
Data point term sent to Coder	System	05 Nov 2020 22:31:08
User entered 'Obstructive Sleep Apnea'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:30:45

**US3292320**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:19:00
User entered 'un UNK 2008'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:30:45

**US3292320**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:19:02
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:30:45



**US3292320**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:19:05
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:30:45

**US3292320**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:19:07
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:30:45

**US3292320**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:19:09
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:30:45

**US3292320**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2008'	System	05 Nov 2020 22:30:45

**US3292320**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:33:11**

**Start Year (derived)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2008'	System	05 Nov 2020 22:30:45

**US3292320**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:30:45

**US3292320**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:30:45

US3292320

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:33:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:19:22
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in joint involving shoulder region - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:48:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:48:29
Data point term sent to Coder	System	05 Nov 2020 22:32:08
User entered 'R Shoulder joint pain'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:31:08



**US3292320**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:19:24
User entered 'un UNK 2004'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:31:08

**US3292320**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:19:26
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:31:08

**US3292320**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:19:27
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:31:08

**US3292320**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:19:29
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:31:08

**US3292320**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:19:31
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:31:08

**US3292320**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2004'	System	05 Nov 2020 22:31:08

**US3292320**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2004'	System	05 Nov 2020 22:31:08

**US3292320**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:31:08



**US3292320**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:31:08

US3292320

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:33:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:19:49
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:32:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 22:32:47
Data point term sent to Coder	System	05 Nov 2020 22:32:08
User entered 'Constipation'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:31:52

**US3292320**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:19:50
User entered 'un UNK 2018'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:31:52

**US3292320**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:19:52
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:31:52

**US3292320**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:19:53
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:31:52

**US3292320**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:19:55
User entered 'un UNK 2018'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:31:52

**US3292320**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:19:57
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:31:52

**US3292320**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2018'	System	05 Nov 2020 22:31:52



**US3292320**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2018'	System	05 Nov 2020 22:31:52

**US3292320**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2018'	System	05 Nov 2020 22:31:52

**US3292320**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2018'	System	05 Nov 2020 22:31:52

US3292320

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:33:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:20:05
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:34:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 22:34:32
Data point term sent to Coder	System	05 Nov 2020 22:33:11
User entered 'Hyperlipidemia'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:32:18

**US3292320**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:20:06
User entered 'un UNK 2018'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:32:18

**US3292320**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:20:08
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:32:18

**US3292320**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:20:10
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:32:18

**US3292320**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:20:12
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:32:18



**US3292320**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:20:13
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:32:18

**US3292320**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2018'	System	05 Nov 2020 22:32:18

**US3292320**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2018'	System	05 Nov 2020 22:32:18

**US3292320**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:32:18

**US3292320**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:32:18

US3292320

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:33:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:20:19
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Cervical spinal cord and nerve root disorders, PT: Cervical radiculopathy, LLT: Cervical radiculopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:34:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 22:34:32
Data point term sent to Coder	System	05 Nov 2020 22:33:13
User entered 'Cervical Radiculopathy'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:32:49

**US3292320**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:20:27
User entered 'un UNK 2008'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:32:49

**US3292320**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:20:29
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:32:49



**US3292320**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:20:30
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:32:49

**US3292320**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:20:32
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:32:49

**US3292320**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:20:34
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 22:32:49

**US3292320**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'Jan 2008'	System	05 Nov 2020 22:32:49

**US3292320**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '2008'	System	05 Nov 2020 22:32:49

**US3292320**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:32:49

**US3292320**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	05 Nov 2020 22:32:49

**US3292320**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:53:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:54:40



US3292320

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:53:52
User entered '25 Aug 2020'		27 Aug 2020 18:54:40

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:53:52
User entered '15:16'		27 Aug 2020 18:54:40

**US3292320**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '25 Aug 2020 15:16'	System	27 Aug 2020 18:54:40

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:53:52
User entered '175.5' cm		27 Aug 2020 18:54:40
DataPoint set to visible.	System	25 Aug 2020 21:39:37

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:53:52
User entered '95.6' kg	(b) (4), (b) (6)	27 Aug 2020 18:54:40
DataPoint set to visible.	System	25 Aug 2020 21:39:37

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
Amendment Manager: User entered '31.03871'	System	17 Sep 2020 00:02:45
User entered '31.0'	System	27 Aug 2020 18:54:40
DataPoint set to visible.	System	25 Aug 2020 21:39:37

**US3292320**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'kg/m2'	System	27 Aug 2020 18:54:40
DataPoint set to visible.	System	25 Aug 2020 21:39:37

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 19:37:54
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 19:48:48
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 19:44:58
Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 18:03:17
User opened query 'Data is required. Please provide.' System (Site from System).		30 Dec 2020 18:03:00
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 18:03:00
User entered empty; reason for change Data Entry Error		30 Dec 2020 18:03:00
DataPoint Verified.		22 Oct 2020 20:53:52
User entered missing code ND - Not Done.		27 Aug 2020 18:54:40



US3292320

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 19:37:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 13:40:30
Query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	21 Dec 2020 19:48:13
DataPoint Un-verified.	(b) (4)	
	Dawn Killian (b) (4)	21 Dec 2020 19:48:05
User entered empty; reason for change Data Entry Error	(b) (4)	
	Dawn Killian (b) (4)	21 Dec 2020 19:48:05
User opened query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 17:24:42
DataPoint Verified.		22 Oct 2020 20:53:52
User entered 'Other (Other)'		27 Aug 2020 18:54:40

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 19:37:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Per CDM: Please remove the data as this field should be "blank".	(b) (4)	30 Dec 2020 19:45:01
' (Site from DM).	(b) (4), (b) (6)	
Query 'Per CDM: Please remove the data as this field should be "blank".		30 Dec 2020 18:03:19
' answered with 'Completed' (Site from DM).		
DataPoint Un-verified.		30 Dec 2020 18:03:00
User entered empty; reason for change Data Entry Error		30 Dec 2020 18:03:00
User opened query 'Per CDM: Please remove the data as this field should be "blank".		23 Dec 2020 13:40:50
' (Site from DM).		
DataPoint Verified.		22 Oct 2020 20:53:52
User entered missing code ND - Not Done.		27 Aug 2020 18:54:40

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 19:37:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query ' <input type="checkbox"/> Per CDM: Response noted. If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done. please update fields.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 22:30:35
Query ' <input type="checkbox"/> Per CDM: Response noted. If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done. please update fields.' answered with 'Completed' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 19:48:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 19:48:48
User opened query ' <input type="checkbox"/> Per CDM: Response noted. If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done. please update fields.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 19:45:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 19:45:03
Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 18:03:22
User opened query 'Data is required. Please provide.' System (Site from System).		30 Dec 2020 18:03:00
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 18:03:00
User entered empty; reason for change Data Entry Error		30 Dec 2020 18:03:00
DataPoint Verified.		22 Oct 2020 20:53:52
User entered missing code ND - Not Done.		27 Aug 2020 18:54:40

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'bpm'	System	30 Dec 2020 19:48:48
User entered empty.	System	30 Dec 2020 18:03:00
User entered 'bpm'	System	27 Aug 2020 18:54:40

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 19:37:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 19:48:48
Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 19:45:21
User opened query 'Data is required. Please provide.' System	(b) (4), (b) (6)	30 Dec 2020 18:03:26
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 18:03:00
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 18:03:00
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:53:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 18:54:40

**US3292320**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'breaths/min'	System	30 Dec 2020 19:48:48
User entered empty.	System	30 Dec 2020 18:03:00
User entered 'breaths/min'	System	27 Aug 2020 18:54:40

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 19:37:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	30 Dec 2020 19:48:48
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 19:45:23
Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 18:03:30
User opened query 'Data is required. Please provide.' System (Site from System).	(b) (4), (b) (6)	30 Dec 2020 18:03:00
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 18:03:00
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 18:03:00
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:53:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 18:54:40

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'mmHg'	System	30 Dec 2020 19:48:48
User entered empty.	System	30 Dec 2020 18:03:00
User entered 'mmHg'	System	27 Aug 2020 18:54:40



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 19:37:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 19:48:48
Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 19:45:25
User opened query 'Data is required. Please provide.' System	(b) (4), (b) (6)	30 Dec 2020 18:03:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 18:03:00
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 18:03:00
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:53:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 18:54:40

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'mmHg'	System	30 Dec 2020 19:48:48
User entered empty.	System	30 Dec 2020 18:03:00
User entered 'mmHg'	System	27 Aug 2020 18:54:40

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01

US3292320

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:33:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:53:57
User entered 'Yes (Y)'		27 Aug 2020 18:54:48

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:33:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:53:57
User entered '25 Aug 2020'		27 Aug 2020 18:54:48

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:12
User entered 'No (N)'		27 Aug 2020 18:55:27

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:12
User entered 'No (N)'		27 Aug 2020 18:55:27



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Folder: Screening

Form: Risk of Exposure

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**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)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:54:12
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:55:27

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Folder: Screening

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**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)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:54:12
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:55:27

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:12
User entered 'No (N)'		27 Aug 2020 18:55:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:33:11

[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)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:12
User entered 'No (N)'		27 Aug 2020 18:55:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:33:11

**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)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:12
User entered 'Yes (Y)'		27 Aug 2020 18:55:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:33:11

[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)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:54:12
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:55:27

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Folder: Screening

Form: Risk of Exposure

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**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)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:54:12
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:55:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:33:11

**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)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:12
User entered 'No (N)'		27 Aug 2020 18:55:27



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Folder: Screening

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**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)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:54:12
User entered 'No (N)'		27 Aug 2020 18:55:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:33:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:12
User entered 'No (N)'		27 Aug 2020 18:55:27

**US3292320**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:33:11**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:54:12
User entered empty.		27 Aug 2020 18:55:27

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:33:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'l'	(b) (4), (b) (6)	27 Aug 2020 18:55:27

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:33:11

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:54:12
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:55:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:33:11

**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)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:54:12
User entered '0'		27 Aug 2020 18:55:27

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:33:11

**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)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:12
User entered '0'		27 Aug 2020 18:55:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:33:11

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)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:54:12
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:55:27



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:54:12
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:55:27

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:33:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:55:27

**US3292320**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:33:11**

**[Specify](#)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:12
User entered empty.		27 Aug 2020 18:55:27

US3292320

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:29
User entered 'Yes (Y)'		27 Aug 2020 18:57:44

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:29
User entered '25 Aug 2020'		27 Aug 2020 18:57:44

US3292320

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

[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 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:29
User entered 'Clinic (Clinic)'		27 Aug 2020 18:57:44

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'VISIT1'	System	27 Aug 2020 18:57:44

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:54:33
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 21:19:17



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:54:33
User entered '108491'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 21:19:17

US3292320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:54:33
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 21:19:17

US3292320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:33:11

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)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:54:33
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:58:16

US3292320

Folder: Visit 1 Day 1

Form: Randomization

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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)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:54:33
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:58:16

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:33
User entered 'No (N)'		27 Aug 2020 18:58:16

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:33:11**

**Diabetes (Type I, Type 2, or gestational)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:54:33
User entered 'No (N)'		27 Aug 2020 18:58:16

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:33:11**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:54:33
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:58:16

US3292320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:33:11

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
DataPoint Verified.	(b) (4)	02 Mar 2021 19:38:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 16:07:16
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	07 Dec 2020 23:19:31
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	07 Dec 2020 23:19:28
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:45:05
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 07:56:01
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:56:00



US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:33:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:55:20
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 19:32:01

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:33:11**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered missing code ND - Not Done.		27 Aug 2020 19:32:01

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:33:11**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered missing code ND - Not Done.		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:33:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered missing code ND - Not Done.		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User accepted default value 'Pre-Dose (PREDOSE)'		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:55:20
User entered 'Yes (Y)'		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered '25 Aug 2020'		27 Aug 2020 19:32:01

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:55:20
User entered '15:22'	(b) (4), (b) (6)	27 Aug 2020 19:32:01



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '25 Aug 2020 15:22'	System	27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered '036.4' C		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:55:20
User entered 'Oral (Oral)'	(b) (4), (b) (6)	7 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:55:20
User entered empty.		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:55:20
User entered '075'		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'bpm'	System	27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered '016'		27 Aug 2020 19:32:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'breaths/min'	System	27 Aug 2020 19:32:01



US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:55:20
User entered '149'		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'mmHg'	System	27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered '089'		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'mmHg'	System	27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:33:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered missing code ND - Not Done.		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:33:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:55:20
User entered missing code ND - Not Done.		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User accepted default value 'Post-Dose (POSTDOSE)'		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:55:20
User entered 'Yes (Y)'		27 Aug 2020 19:32:01



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered '25 Aug 2020'		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:55:20
User entered '17:06'	(b) (4), (b) (6)	27 Aug 2020 19:32:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '25 Aug 2020 17:06'	System	27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered '36.6' C		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:55:20
User entered 'Oral (Oral)'		27 Aug 2020 19:32:01

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:33:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered empty.		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered '67'		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'bpm'	System	27 Aug 2020 19:32:01



US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered '16'		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'breaths/min'	System	27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:55:20
User entered '128'		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'mmHg'	System	27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:20
User entered '80'		27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'mmHg'	System	27 Aug 2020 19:32:01

US3292320

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:33:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:59
User entered 'No (N)'		27 Aug 2020 19:32:07

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:33:11**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:55:59
User entered empty.		27 Aug 2020 19:32:07



**US3292320**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:33:11**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:56:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 21:40:04

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:33:11**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:56:03
User entered empty.		25 Aug 2020 21:40:04

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

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 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:56:03
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 21:40:04

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 21:40:04

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:56:03
User entered '25 Aug 2020'		25 Aug 2020 21:40:04

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:56:03
User entered '16:31'	(b) (4), (b) (6)	25 Aug 2020 21:40:04

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:33:11**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '25 Aug 2020 16:31'	System	25 Aug 2020 21:40:04

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:33:11**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:56:03
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	25 Aug 2020 21:40:04



US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
DataPoint Verified.		22 Oct 2020 20:56:03
User entered 'ONCE'	System	25 Aug 2020 21:40:04

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 21:40:04

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:33:11**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:56:45
User entered 'Yes (Y)'		27 Aug 2020 19:33:34

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:33:11**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:56:45
User entered '25 Aug 2020'		27 Aug 2020 19:33:34

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:33:11**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:56:45
User entered '15:29'		27 Aug 2020 19:33:34

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '25 Aug 2020 15:29'	System	27 Aug 2020 19:33:34

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 16:33:11**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:56:51
User entered '25 Aug 2020'		27 Aug 2020 19:33:47

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		27 Aug 2020 19:33:47



US3292320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:33:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:56:51
User entered 'Yes (Y)'		27 Aug 2020 19:33:47

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:56:51
User entered '15:45'		27 Aug 2020 19:33:47

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered '25 Aug 2020 15:45'	System	27 Aug 2020 19:33:47

US3292320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:33:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		27 Aug 2020 19:33:47

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:56:51
User entered 'No (N)'		27 Aug 2020 19:33:47

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 22 Oct 2020 20:56:51
User entered empty.		27 Aug 2020 19:33:47

**US3292320**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered empty.	System	27 Aug 2020 19:33:47

US3292320

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:33:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
DataPoint Verified.		02 Mar 2021 19:38:13
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 19:33:52



**US3292320**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'l'	System	27 Aug 2020 19:33:52

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:08:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b342c84-b060-44d9-9a38-528ea5ec4438' User entered 'Yes (Y)'	System	25 Aug 2020 22:09:59
	System	25 Aug 2020 22:09:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:09:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b342c84-b060-44d9-9a38-528ea5ec4438' User entered '97.9'	System	25 Aug 2020 22:09:59
	System	25 Aug 2020 22:09:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:09:55', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b342c84-b060-44d9-9a38-528ea5ec4438'	System	25 Aug 2020 22:09:59
User entered 'No (N)'	System	25 Aug 2020 22:09:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:09:58', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b342c84-b060-44d9-9a38-528ea5ec4438' User entered '25 Aug 2020 17:09'	System	25 Aug 2020 22:09:59
	System	25 Aug 2020 22:09:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Aug 2020 16:51'	System	25 Aug 2020 21:40:04

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Aug 2020 19:21'	System	25 Aug 2020 21:40:04



US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:29:09', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fc641203-5b9f-4fa9-9807-7098dba03b92'	System	26 Aug 2020 02:31:59
User entered 'Yes (Y)'	System	26 Aug 2020 02:31:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:31:50', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fc641203-5b9f-4fa9-9807-7098dba03b92' User entered '98.7'	System	26 Aug 2020 02:31:59
	System	26 Aug 2020 02:31:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:31:54', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fc641203-5b9f-4fa9-9807-7098dba03b92'	System	26 Aug 2020 02:31:59
User entered 'No (N)'	System	26 Aug 2020 02:31:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:31:56', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fc641203-5b9f-4fa9-9807-7098dba03b92'	System	26 Aug 2020 02:31:59
User entered '25 Aug 2020 21:31'	System	26 Aug 2020 02:31:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Aug 2020 20:16'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 2'	System	25 Aug 2020 21:40:04



US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '699e1356-2c6d-4a87-8be0-99c21967632a' User entered 'Yes (Y)'	System	27 Aug 2020 05:06:27
	System	27 Aug 2020 05:06:27

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '699e1356-2c6d-4a87-8be0-99c21967632a' User entered '98.7'	System	27 Aug 2020 05:06:27
	System	27 Aug 2020 05:06:27

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '699e1356-2c6d-4a87-8be0-99c21967632a' User entered 'No (N)'	System	27 Aug 2020 05:06:27
	System	27 Aug 2020 05:06:27

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:26', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '699e1356-2c6d-4a87-8be0-99c21967632a' User entered '27 Aug 2020 00:06'	System	27 Aug 2020 05:06:27
	System	27 Aug 2020 05:06:27

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 3'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:25', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '2408a021-04d4-4f34-bd1f-c499f35a2fe0' User entered 'Yes (Y)'	System	28 Aug 2020 07:00:50
	System	28 Aug 2020 07:00:50



US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:38', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '2408a021-04d4-4f34-bd1f-c499f35a2fe0' User entered '98.5'	System	28 Aug 2020 07:00:50
	System	28 Aug 2020 07:00:50

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:42', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '2408a021-04d4-4f34-bd1f-c499f35a2fe0'	System	28 Aug 2020 07:00:50
User entered 'No (N)'	System	28 Aug 2020 07:00:50

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:46', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '2408a021-04d4-4f34-bd1f-c499f35a2fe0' User entered '28 Aug 2020 02:00'	System	28 Aug 2020 07:00:50
	System	28 Aug 2020 07:00:50

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 4'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:32:37', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9a819c4b-9000-4f0c-9303-d9e478c2f3aa' User entered 'Yes (Y)'	System	29 Aug 2020 05:33:12
	System	29 Aug 2020 05:33:12

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:01', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9a819c4b-9000-4f0c-9303-d9e478c2f3aa' User entered '98.7'	System	29 Aug 2020 05:33:12
	System	29 Aug 2020 05:33:12



US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:04', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9a819c4b-9000-4f0c-9303-d9e478c2f3aa'	System	29 Aug 2020 05:33:12
User entered 'No (N)'	System	29 Aug 2020 05:33:12

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9a819c4b-9000-4f0c-9303-d9e478c2f3aa' User entered '29 Aug 2020 00:33'	System	29 Aug 2020 05:33:12
	System	29 Aug 2020 05:33:12

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 5'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8d41e26e-0f6c-4e80-a64c-af02c62376b7' User entered 'Yes (Y)'	System	30 Aug 2020 03:30:34
	System	30 Aug 2020 03:30:34

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:24', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8d41e26e-0f6c-4e80-a64c-af02c62376b7' User entered '96.7'	System	30 Aug 2020 03:30:34
	System	30 Aug 2020 03:30:34

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:27', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8d41e26e-0f6c-4e80-a64c-af02c62376b7'	System	30 Aug 2020 03:30:34
User entered 'No (N)'	System	30 Aug 2020 03:30:34



US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:31', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8d41e26e-0f6c-4e80-a64c-af02c62376b7' User entered '29 Aug 2020 22:30'	System	30 Aug 2020 03:30:34
	System	30 Aug 2020 03:30:34

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 6'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:08', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a3609f78-04ae-43b4-a2b1-728ce02a9a37'	System	30 Aug 2020 18:14:21
User entered 'Yes (Y)'	System	30 Aug 2020 18:14:21

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:13', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a3609f78-04ae-43b4-a2b1-728ce02a9a37' User entered '97.4'	System	30 Aug 2020 18:14:21
	System	30 Aug 2020 18:14:21

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a3609f78-04ae-43b4-a2b1-728ce02a9a37'	System	30 Aug 2020 18:14:21
User entered 'No (N)'	System	30 Aug 2020 18:14:21

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a3609f78-04ae-43b4-a2b1-728ce02a9a37'	System	30 Aug 2020 18:14:21
User entered '30 Aug 2020 13:14'	System	30 Aug 2020 18:14:21



**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 7'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '4faa2baf-6217-4783-92c8-2ae454b9ca65' User entered 'Yes (Y)'	System	01 Sep 2020 03:41:13
	System	01 Sep 2020 03:41:13

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:05', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '4faa2baf-6217-4783-92c8-2ae454b9ca65' User entered '97.4'	System	01 Sep 2020 03:41:13
	System	01 Sep 2020 03:41:13

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:08', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '4faa2baf-6217-4783-92c8-2ae454b9ca65'	System	01 Sep 2020 03:41:13
User entered 'No (N)'	System	01 Sep 2020 03:41:13

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '4faa2baf-6217-4783-92c8-2ae454b9ca65'	System	01 Sep 2020 03:41:13
User entered '31 Aug 2020 22:41'	System	01 Sep 2020 03:41:13

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 21:40:04



US3292320

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:06:32', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0596171c-1b9a-4029-bf6d-ab700bdd82bc' User entered 'None (1)'	System	25 Aug 2020 22:07:04
	System	25 Aug 2020 22:07:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:06:35', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0596171c-1b9a-4029-bf6d-ab700bdd82bc' User entered 'No (N)'	System	25 Aug 2020 22:07:04
	System	25 Aug 2020 22:07:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:06:43', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0596171c-1b9a-4029-bf6d-ab700bdd82bc' User entered 'No (N)'	System	25 Aug 2020 22:07:04
	System	25 Aug 2020 22:07:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:06:50', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0596171c-1b9a-4029-bf6d-ab700bdd82bc' User entered 'None (1)'	System	25 Aug 2020 22:07:04
	System	25 Aug 2020 22:07:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:07:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0596171c-1b9a-4029-bf6d-ab700bdd82bc' User entered '25 Aug 2020 17:07'	System	25 Aug 2020 22:07:04
	System	25 Aug 2020 22:07:04

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Aug 2020 16:51'	System	25 Aug 2020 21:40:04



**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Aug 2020 19:21'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:05', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f613da89-eef5-4967-83a4-91eb6d6089f6'	System	26 Aug 2020 02:32:21
User entered 'None (1)'	System	26 Aug 2020 02:32:21

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:09', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f613da89-eef5-4967-83a4-91eb6d6089f6'	System	26 Aug 2020 02:32:21
User entered 'No (N)'	System	26 Aug 2020 02:32:21

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:12', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f613da89-eef5-4967-83a4-91eb6d6089f6'	System	26 Aug 2020 02:32:21
User entered 'No (N)'	System	26 Aug 2020 02:32:21

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f613da89-eef5-4967-83a4-91eb6d6089f6'	System	26 Aug 2020 02:32:21
User entered 'None (1)'	System	26 Aug 2020 02:32:21

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:20', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f613da89-eef5-4967-83a4-91eb6d6089f6' User entered '25 Aug 2020 21:32'	System	26 Aug 2020 02:32:21
	System	26 Aug 2020 02:32:21

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Aug 2020 20:16'	System	25 Aug 2020 21:40:04



US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 2'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '239def3c-5b16-4fa5-a09a-5ea915c4f1d1' User entered 'None (1)'	System	27 Aug 2020 05:06:47
	System	27 Aug 2020 05:06:47

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:33', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '239def3c-5b16-4fa5-a09a-5ea915c4f1d1'	System	27 Aug 2020 05:06:47
User entered 'No (N)'	System	27 Aug 2020 05:06:47

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:38', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '239def3c-5b16-4fa5-a09a-5ea915c4f1d1' User entered 'No (N)'	System	27 Aug 2020 05:06:47
	System	27 Aug 2020 05:06:47

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:42', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '239def3c-5b16-4fa5-a09a-5ea915c4f1d1' User entered 'None (1)'	System	27 Aug 2020 05:06:47
	System	27 Aug 2020 05:06:47

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:45', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '239def3c-5b16-4fa5-a09a-5ea915c4f1d1' User entered '27 Aug 2020 00:06'	System	27 Aug 2020 05:06:47
	System	27 Aug 2020 05:06:47

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 21:40:04



**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 3'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:05', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6166d662-2fb1-4ec5-ad44-a30bd1b292d3' User entered 'None (1)'	System	28 Aug 2020 07:00:23
	System	28 Aug 2020 07:00:23

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:08', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6166d662-2fb1-4ec5-ad44-a30bd1b292d3' User entered 'No (N)'	System	28 Aug 2020 07:00:23
	System	28 Aug 2020 07:00:23

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6166d662-2fb1-4ec5-ad44-a30bd1b292d3' User entered 'No (N)'	System	28 Aug 2020 07:00:23
	System	28 Aug 2020 07:00:23

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:14', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6166d662-2fb1-4ec5-ad44-a30bd1b292d3' User entered 'None (1)'	System	28 Aug 2020 07:00:23
	System	28 Aug 2020 07:00:23

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6166d662-2fb1-4ec5-ad44-a30bd1b292d3' User entered '28 Aug 2020 02:00'	System	28 Aug 2020 07:00:23
	System	28 Aug 2020 07:00:23

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 21:40:04



US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 4'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:12', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c3212415-d606-4f47-bf6d-1cdf696d98d9'	System	29 Aug 2020 05:33:28
User entered 'None (1)'	System	29 Aug 2020 05:33:28

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c3212415-d606-4f47-bf6d-1cdf696d98d9'	System	29 Aug 2020 05:33:28
User entered 'No (N)'	System	29 Aug 2020 05:33:28

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:18', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c3212415-d606-4f47-bf6d-1cdf696d98d9' User entered 'No (N)'	System	29 Aug 2020 05:33:28
	System	29 Aug 2020 05:33:28

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:24', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c3212415-d606-4f47-bf6d-1cdf696d98d9'	System	29 Aug 2020 05:33:28
User entered 'None (1)'	System	29 Aug 2020 05:33:28

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:27', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c3212415-d606-4f47-bf6d-1cdf696d98d9' User entered '29 Aug 2020 00:33'	System	29 Aug 2020 05:33:28
	System	29 Aug 2020 05:33:28

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 21:40:04



US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 5'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:44', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f98cd639-475a-4619-87d4-041a2abcd7b9'	System	30 Aug 2020 03:30:56
User entered 'None (1)'	System	30 Aug 2020 03:30:56

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:46', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f98cd639-475a-4619-87d4-041a2abcd7b9' User entered 'No (N)'	System	30 Aug 2020 03:30:56
	System	30 Aug 2020 03:30:56

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:48', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f98cd639-475a-4619-87d4-041a2abcd7b9'	System	30 Aug 2020 03:30:56
User entered 'No (N)'	System	30 Aug 2020 03:30:56

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f98cd639-475a-4619-87d4-041a2abcd7b9' User entered 'None (1)'	System	30 Aug 2020 03:30:56
	System	30 Aug 2020 03:30:56

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f98cd639-475a-4619-87d4-041a2abcd7b9' User entered '29 Aug 2020 22:30'	System	30 Aug 2020 03:30:56
	System	30 Aug 2020 03:30:56

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 21:40:04



**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 6'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:20', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '778d3237-87a2-44db-8733-3b912c3e55fc' User entered 'None (1)'	System	30 Aug 2020 18:14:34
	System	30 Aug 2020 18:14:34

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '778d3237-87a2-44db-8733-3b912c3e55fc'	System	30 Aug 2020 18:14:34
User entered 'No (N)'	System	30 Aug 2020 18:14:34

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:23', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '778d3237-87a2-44db-8733-3b912c3e55fc'	System	30 Aug 2020 18:14:34
User entered 'No (N)'	System	30 Aug 2020 18:14:34

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:25', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '778d3237-87a2-44db-8733-3b912c3e55fc' User entered 'None (1)'	System	30 Aug 2020 18:14:34
	System	30 Aug 2020 18:14:34

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:27', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '778d3237-87a2-44db-8733-3b912c3e55fc' User entered '30 Aug 2020 13:14'	System	30 Aug 2020 18:14:34
	System	30 Aug 2020 18:14:34

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 21:40:04



**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 7'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:14', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '455c509b-b3bc-494e-9de9-7e7ffd0fe04c'	System	01 Sep 2020 03:42:16
User entered 'None (1)'	System	01 Sep 2020 03:42:16

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '455c509b-b3bc-494e-9de9-7e7ffd0fe04c' User entered 'No (N)'	System	01 Sep 2020 03:42:16
	System	01 Sep 2020 03:42:16

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '455c509b-b3bc-494e-9de9-7e7ffd0fe04c' User entered 'No (N)'	System	01 Sep 2020 03:42:16
	System	01 Sep 2020 03:42:16

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:21', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '455c509b-b3bc-494e-9de9-7e7ffd0fe04c' User entered 'None (1)'	System	01 Sep 2020 03:42:16
	System	01 Sep 2020 03:42:16

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:14', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '455c509b-b3bc-494e-9de9-7e7ffd0fe04c' User entered '31 Aug 2020 22:42'	System	01 Sep 2020 03:42:16
	System	01 Sep 2020 03:42:16

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 21:40:04



**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' User entered 'None (0)'	System	25 Aug 2020 22:10:34
	System	25 Aug 2020 22:10:34

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' User entered 'None (0)'	System	25 Aug 2020 22:10:34
	System	25 Aug 2020 22:10:34

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:16', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' User entered 'None (0)'	System	25 Aug 2020 22:10:34
	System	25 Aug 2020 22:10:34

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' User entered 'None (0)'	System	25 Aug 2020 22:10:34
	System	25 Aug 2020 22:10:34

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' User entered 'None (0)'	System	25 Aug 2020 22:10:34
	System	25 Aug 2020 22:10:34

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:24', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' User entered 'None (0)'	System	25 Aug 2020 22:10:34
	System	25 Aug 2020 22:10:34



US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:28', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4'	System	25 Aug 2020 22:10:34
User entered 'No (N)'	System	25 Aug 2020 22:10:34

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:31', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' User entered '25 Aug 2020 17:10'	System	25 Aug 2020 22:10:34
	System	25 Aug 2020 22:10:34

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Aug 2020 16:51'	System	25 Aug 2020 21:40:04

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Aug 2020 19:21'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:26', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed'	System	26 Aug 2020 02:32:58
User entered 'None (0)'	System	26 Aug 2020 02:32:58

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:29', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed'	System	26 Aug 2020 02:32:58
User entered 'None (0)'	System	26 Aug 2020 02:32:58

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:32', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed' User entered 'None (0)'	System	26 Aug 2020 02:32:58
	System	26 Aug 2020 02:32:58



US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:34', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed'	System	26 Aug 2020 02:32:58
User entered 'None (0)'	System	26 Aug 2020 02:32:58

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:36', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed' User entered 'None (0)'	System	26 Aug 2020 02:32:58
	System	26 Aug 2020 02:32:58

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:39', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed' User entered 'None (0)'	System	26 Aug 2020 02:32:58
	System	26 Aug 2020 02:32:58

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed'	System	26 Aug 2020 02:32:58
User entered 'No (N)'	System	26 Aug 2020 02:32:58

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed'	System	26 Aug 2020 02:32:58
User entered '25 Aug 2020 21:32'	System	26 Aug 2020 02:32:58

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Aug 2020 20:16'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 2'	System	25 Aug 2020 21:40:04



US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:50', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' User entered 'None (0)'	System	27 Aug 2020 05:07:11
	System	27 Aug 2020 05:07:11

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' User entered 'None (0)'	System	27 Aug 2020 05:07:11
	System	27 Aug 2020 05:07:11

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:55', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' User entered 'None (0)'	System	27 Aug 2020 05:07:11
	System	27 Aug 2020 05:07:11

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:59', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' User entered 'None (0)'	System	27 Aug 2020 05:07:11
	System	27 Aug 2020 05:07:11

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:07:01', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' User entered 'None (0)'	System	27 Aug 2020 05:07:11
	System	27 Aug 2020 05:07:11

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:33:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:07:03', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' User entered 'None (0)'	System	27 Aug 2020 05:07:11
	System	27 Aug 2020 05:07:11

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:07:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' User entered 'No (N)'	System	27 Aug 2020 05:07:11
	System	27 Aug 2020 05:07:11

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:07:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' User entered '27 Aug 2020 00:07'	System	27 Aug 2020 05:07:11
	System	27 Aug 2020 05:07:11



**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 21:40:04

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 3'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:50', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' User entered 'None (0)'	System	28 Aug 2020 07:01:07
	System	28 Aug 2020 07:01:07

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' User entered 'None (0)'	System	28 Aug 2020 07:01:07
	System	28 Aug 2020 07:01:07

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' User entered 'None (0)'	System	28 Aug 2020 07:01:07
	System	28 Aug 2020 07:01:07

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:55', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' User entered 'None (0)'	System	28 Aug 2020 07:01:07
	System	28 Aug 2020 07:01:07

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:57', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' User entered 'None (0)'	System	28 Aug 2020 07:01:07
	System	28 Aug 2020 07:01:07



**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:33:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:59', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' User entered 'None (0)'	System	28 Aug 2020 07:01:07
	System	28 Aug 2020 07:01:07

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:01:02', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' User entered 'No (N)'	System	28 Aug 2020 07:01:07
	System	28 Aug 2020 07:01:07

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:01:04', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' User entered '28 Aug 2020 02:01'	System	28 Aug 2020 07:01:07
	System	28 Aug 2020 07:01:07

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 21:40:04

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 4'	System	25 Aug 2020 21:40:04

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:33:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:34', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' User entered 'None (0)'	System	29 Aug 2020 05:34:15
	System	29 Aug 2020 05:34:15

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:36', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' User entered 'None (0)'	System	29 Aug 2020 05:34:15
	System	29 Aug 2020 05:34:15



US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:39', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' User entered 'None (0)'	System	29 Aug 2020 05:34:15
	System	29 Aug 2020 05:34:15

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:45', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' User entered 'None (0)'	System	29 Aug 2020 05:34:15
	System	29 Aug 2020 05:34:15

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:48', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' User entered 'None (0)'	System	29 Aug 2020 05:34:15
	System	29 Aug 2020 05:34:15

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' User entered 'None (0)'	System	29 Aug 2020 05:34:15
	System	29 Aug 2020 05:34:15

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:56', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' User entered 'No (N)'	System	29 Aug 2020 05:34:15
	System	29 Aug 2020 05:34:15

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:34:13', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' User entered '29 Aug 2020 00:34'	System	29 Aug 2020 05:34:15
	System	29 Aug 2020 05:34:15

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 21:40:04

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 21:40:04



US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 5'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:09', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537'	System	30 Aug 2020 03:31:32
User entered 'None (0)'	System	30 Aug 2020 03:31:32

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537'	System	30 Aug 2020 03:31:32
User entered 'None (0)'	System	30 Aug 2020 03:31:32

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:13', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537' User entered 'None (0)'	System	30 Aug 2020 03:31:32
	System	30 Aug 2020 03:31:32

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537' User entered 'None (0)'	System	30 Aug 2020 03:31:32
	System	30 Aug 2020 03:31:32

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537' User entered 'None (0)'	System	30 Aug 2020 03:31:32
	System	30 Aug 2020 03:31:32

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537' User entered 'None (0)'	System	30 Aug 2020 03:31:32
	System	30 Aug 2020 03:31:32

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:28', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537'	System	30 Aug 2020 03:31:32
User entered 'No (N)'	System	30 Aug 2020 03:31:32



US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537'	System	30 Aug 2020 03:31:32
User entered '29 Aug 2020 22:31'	System	30 Aug 2020 03:31:32

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 21:40:04

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 6'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' User entered 'None (0)'	System	30 Aug 2020 18:14:48
	System	30 Aug 2020 18:14:48

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:33', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' User entered 'None (0)'	System	30 Aug 2020 18:14:48
	System	30 Aug 2020 18:14:48

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:34', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' User entered 'None (0)'	System	30 Aug 2020 18:14:48
	System	30 Aug 2020 18:14:48

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:35', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' User entered 'None (0)'	System	30 Aug 2020 18:14:48
	System	30 Aug 2020 18:14:48



US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:37', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' User entered 'None (0)'	System	30 Aug 2020 18:14:48
	System	30 Aug 2020 18:14:48

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:39', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' User entered 'None (0)'	System	30 Aug 2020 18:14:48
	System	30 Aug 2020 18:14:48

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:44', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' User entered 'No (N)'	System	30 Aug 2020 18:14:48
	System	30 Aug 2020 18:14:48

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:46', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' User entered '30 Aug 2020 13:14'	System	30 Aug 2020 18:14:48
	System	30 Aug 2020 18:14:48

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 21:40:04

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 7'	System	25 Aug 2020 21:40:04

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:33:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:18', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' User entered 'None (0)'	System	01 Sep 2020 03:42:34
	System	01 Sep 2020 03:42:34



US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:20', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' User entered 'None (0)'	System	01 Sep 2020 03:42:34
	System	01 Sep 2020 03:42:34

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' User entered 'None (0)'	System	01 Sep 2020 03:42:34
	System	01 Sep 2020 03:42:34

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:23', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' User entered 'None (0)'	System	01 Sep 2020 03:42:34
	System	01 Sep 2020 03:42:34

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:25', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' User entered 'None (0)'	System	01 Sep 2020 03:42:34
	System	01 Sep 2020 03:42:34

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:27', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' User entered 'None (0)'	System	01 Sep 2020 03:42:34
	System	01 Sep 2020 03:42:34

US3292320

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:29', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' User entered 'No (N)'	System	01 Sep 2020 03:42:34
	System	01 Sep 2020 03:42:34

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:31', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' User entered '31 Aug 2020 22:42'	System	01 Sep 2020 03:42:34
	System	01 Sep 2020 03:42:34

**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 21:40:04



**US3292320**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:47:14
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	30 Sep 2020 18:25:01
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	28 Sep 2020 20:15:20
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	24 Sep 2020 17:50:36
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	24 Sep 2020 15:02:05
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:02:05

**US3292320**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:47:14
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:02:05

US3292320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:47:14
User entered empty; reason for change Data Entry Error	Dawn Killian (b) (4)	30 Sep 2020 18:25:01
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 20:15:20
User entered empty; reason for change Data Entry Error	Dawn Killian (b) (4)	24 Sep 2020 17:50:36
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	24 Sep 2020 15:02:05

US3292320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	22 Oct 2020 20:47:14
User entered 'CONTACT NOT MADE DUE TO ERROR' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 20:15:20
User closed query 'The Contact Status is 'CONTACT System NOT MADE'; however, Comments have not been provided.		24 Sep 2020 17:50:20
Please review and reconcile.' (Site from System).		
User entered 'Not done' reason for change: Data Entry Error	Dawn Killian (b) (4)	24 Sep 2020 17:50:20
User opened query 'The Contact Status is 'CONTACT System NOT MADE'; however, Comments have not been provided.	(b) (4)	24 Sep 2020 15:02:05
Please review and reconcile.' (Site from System).		
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:02:05

US3292320

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:33:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:47:19
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	09 Sep 2020 16:51:02

US3292320

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:33:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'l'	System	09 Sep 2020 16:51:02

**US3292320**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:47:01
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	09 Sep 2020 16:51:12



US3292320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Un-verified.	(b) (4)	
	Antonio Gutierrez (b) (4)	10 Nov 2020 15:45:08
User entered '09 Sep 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 15:45:08
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:47:01
User entered '9 Sep 2020'	Kristy Trevino (b) (4)	09 Sep 2020 16:51:12
	(b) (4)	

US3292320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:47:01
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4)	09 Sep 2020 16:51:12

US3292320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:47:01
User entered empty.	Kristy Trevino (b) (4)	09 Sep 2020 16:51:12

**US3292320**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:37:15
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	09 Sep 2020 17:05:42

**US3292320**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'I'	System	09 Sep 2020 17:05:42

**US3292320**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:28:39
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	25 Sep 2020 17:09:09

US3292320

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:28:39
User entered '15 Sep 2020'	Gerardo Pena (b) (4)	25 Sep 2020 17:09:09

**US3292320**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:28:39
User entered 'Contact Made (CONTACT MADE)'	Gerardo Pena (b) (4)	25 Sep 2020 17:09:09



US3292320

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:28:39
User entered empty.	Gerardo Pena (b) (4)	25 Sep 2020 17:09:09

**US3292320**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:28:42
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	22 Sep 2020 20:35:19

**US3292320**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:04:01
User entered 'l'	System	22 Sep 2020 20:35:19

US3292320

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:53:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:20:55

**US3292320**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:53:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '22 Sep 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:20:55

**US3292320**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[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 22:48:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:53:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:20:55

**US3292320**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'VISIT2'	System	22 Sep 2020 21:20:55

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User accepted default value 'Pre-Dose (PREDOSE)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:21:32



US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.	(b) (4)	19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.	(b) (4)	19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '22 Sep 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '14:17'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered '22 Sep 2020 14:17'	System	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.7' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '79'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:21:32



US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'bpm'	System	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '12'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'breaths/min'	System	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '134'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'mmHg'	System	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '84'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:33:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'mmHg'	System	22 Sep 2020 21:21:32

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User accepted default value 'Post-Dose (POSTDOSE)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:04



US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '22 Sep 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.	(b) (4)	19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '16:00'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered '22 Sep 2020 16:00'	System	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.1' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '82'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:04



US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'bpm'	System	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '12'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'breaths/min'	System	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '131'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'mmHg'	System	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '96'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:33:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'mmHg'	System	22 Sep 2020 21:22:04

US3292320

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:33:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:23



US3292320

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:33:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '22 Sep 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:23

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:54
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	22 Sep 2020 20:35:38

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:54:54
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	22 Sep 2020 20:35:38

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

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)	27 Apr 2021 22:48:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:54:54
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	22 Sep 2020 20:35:38

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 20:35:38

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:54
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '22 Sep 2020'	(b) (4) Nathan Cortez (b) (4)	22 Sep 2020 20:35:38

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:54
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '15:30'	(b) (4) Nathan Cortez (b) (4)	22 Sep 2020 20:35:38

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered '22 Sep 2020 15:30'	System	22 Sep 2020 20:35:38



US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:54:54
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Left Arm (LEFT ARM)'	(b) (4) Nathan Cortez (b) (4)	22 Sep 2020 20:35:38

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:54:54
User entered 'ONCE'	System	22 Sep 2020 20:35:38

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:33:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 20:35:38

US3292320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:33:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:55:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:40

US3292320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:33:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:55:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '22 Sep 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:40

US3292320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:33:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:55:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '14:25'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:22:40

**US3292320**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered '22 Sep 2020 14:25'	System	22 Sep 2020 21:22:40

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:33:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:55:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '22 Sep 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:23:09



**US3292320**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:23:09

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:33:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:55:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:23:09

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:33:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		19 Apr 2021 15:55:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '14:42'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:23:09

**US3292320**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered '22 Sep 2020 14:42'	System	22 Sep 2020 21:23:09

**US3292320**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:23:09

**US3292320**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:55:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:23:09

**US3292320**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.	(b) (4)	19 Apr 2021 15:55:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:23:09

**US3292320**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered empty.	System	22 Sep 2020 21:23:09



US3292320

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:33:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		16 Apr 2021 20:43:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 21:23:15

US3292320

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:33:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'l'	System	22 Sep 2020 21:23:15

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:02:42', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6c4d9f84-14df-4ff7-8d31-e7f80faf77a9'	System	22 Sep 2020 21:02:59
User entered 'Yes (Y)'	System	22 Sep 2020 21:02:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:02:49', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6c4d9f84-14df-4ff7-8d31-e7f80faf77a9'	System	22 Sep 2020 21:02:59
User entered '97.0'	System	22 Sep 2020 21:02:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:02:52', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6c4d9f84-14df-4ff7-8d31-e7f80faf77a9'	System	22 Sep 2020 21:02:59
User entered 'No (N)'	System	22 Sep 2020 21:02:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:02:57', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6c4d9f84-14df-4ff7-8d31-e7f80faf77a9'	System	22 Sep 2020 21:02:59
User entered '22 Sep 2020 16:02'	System	22 Sep 2020 21:02:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '22 Sep 2020 15:50'	System	22 Sep 2020 20:35:38



US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '22 Sep 2020 18:20'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:32', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a71973ff-c795-4fa2-afda-c2848d746376' User entered 'Yes (Y)'	System	23 Sep 2020 08:37:49
	System	23 Sep 2020 08:37:49

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:37', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a71973ff-c795-4fa2-afda-c2848d746376' User entered '97.4'	System	23 Sep 2020 08:37:49
	System	23 Sep 2020 08:37:49

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:41', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a71973ff-c795-4fa2-afda-c2848d746376'	System	23 Sep 2020 08:37:49
User entered 'No (N)'	System	23 Sep 2020 08:37:49

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:47', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a71973ff-c795-4fa2-afda-c2848d746376' User entered '23 Sep 2020 03:37'	System	23 Sep 2020 08:37:49
	System	23 Sep 2020 08:37:49

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '22 Sep 2020 19:15'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 20:35:38



US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 2'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '967cac67-879e-482f-9bc0-e4869243b842'	System	24 Sep 2020 00:29:25
User entered 'Yes (Y)'	System	24 Sep 2020 00:29:25

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '967cac67-879e-482f-9bc0-e4869243b842' User entered '97.1'	System	24 Sep 2020 00:29:25
	System	24 Sep 2020 00:29:25

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '967cac67-879e-482f-9bc0-e4869243b842'	System	24 Sep 2020 00:29:25
User entered 'No (N)'	System	24 Sep 2020 00:29:25

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:20', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '967cac67-879e-482f-9bc0-e4869243b842' User entered '23 Sep 2020 19:29'	System	24 Sep 2020 00:29:25
	System	24 Sep 2020 00:29:25

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 3'	System	22 Sep 2020 20:35:38



US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:37:42', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '7de28a99-2ad0-4eda-9926-dfda128f28fb' User entered 'Yes (Y)'	System	25 Sep 2020 07:38:06
	System	25 Sep 2020 07:38:06

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:37:46', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '7de28a99-2ad0-4eda-9926-dfda128f28fb' User entered '98.0'	System	25 Sep 2020 07:38:06
	System	25 Sep 2020 07:38:06

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:37:55', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '7de28a99-2ad0-4eda-9926-dfda128f28fb' User entered 'No (N)'	System	25 Sep 2020 07:38:06
	System	25 Sep 2020 07:38:06

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:01', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '7de28a99-2ad0-4eda-9926-dfda128f28fb' User entered '25 Sep 2020 02:38'	System	25 Sep 2020 07:38:06
	System	25 Sep 2020 07:38:06

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 4'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:24', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '1a63cb07-5284-4cef-9eb2-e7e9c5408360' User entered 'Yes (Y)'	System	26 Sep 2020 01:46:41
	System	26 Sep 2020 01:46:41



US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:31', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '1a63cb07-5284-4cef-9eb2-e7e9c5408360' User entered '98.1'	System	26 Sep 2020 01:46:41
	System	26 Sep 2020 01:46:41

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:35', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '1a63cb07-5284-4cef-9eb2-e7e9c5408360'	System	26 Sep 2020 01:46:41
User entered 'No (N)'	System	26 Sep 2020 01:46:41

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:39', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '1a63cb07-5284-4cef-9eb2-e7e9c5408360' User entered '25 Sep 2020 20:46'	System	26 Sep 2020 01:46:41
	System	26 Sep 2020 01:46:41

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 5'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:39', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '73d7dd56-e322-4117-a112-03d1cb45e73e' User entered 'Yes (Y)'	System	27 Sep 2020 04:10:53
	System	27 Sep 2020 04:10:53

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:44', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '73d7dd56-e322-4117-a112-03d1cb45e73e' User entered '98.4'	System	27 Sep 2020 04:10:53
	System	27 Sep 2020 04:10:53



US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:47', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '73d7dd56-e322-4117-a112-03d1cb45e73e' User entered 'No (N)'	System	27 Sep 2020 04:10:53
	System	27 Sep 2020 04:10:53

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '73d7dd56-e322-4117-a112-03d1cb45e73e' User entered '26 Sep 2020 23:10'	System	27 Sep 2020 04:10:53
	System	27 Sep 2020 04:10:53

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 6'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:42:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd0d7d38a-13c0-407d-8a21-451ffb126144'	System	28 Sep 2020 05:43:06
User entered 'Yes (Y)'	System	28 Sep 2020 05:43:06

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:42:58', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd0d7d38a-13c0-407d-8a21-451ffb126144' User entered '97.6'	System	28 Sep 2020 05:43:06
	System	28 Sep 2020 05:43:06

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:01', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd0d7d38a-13c0-407d-8a21-451ffb126144'	System	28 Sep 2020 05:43:06
User entered 'No (N)'	System	28 Sep 2020 05:43:06



US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:04', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd0d7d38a-13c0-407d-8a21-451ffb126144' User entered '28 Sep 2020 00:43'	System	28 Sep 2020 05:43:06
	System	28 Sep 2020 05:43:06

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 7'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:36:59', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0b0cecec-49f1-4ffa-808e-9ac87c6212e4'	System	29 Sep 2020 04:37:31
User entered 'Yes (Y)'	System	29 Sep 2020 04:37:31

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:12', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0b0cecec-49f1-4ffa-808e-9ac87c6212e4' User entered '97.7'	System	29 Sep 2020 04:37:31
	System	29 Sep 2020 04:37:31

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0b0cecec-49f1-4ffa-808e-9ac87c6212e4' User entered 'No (N)'	System	29 Sep 2020 04:37:31
	System	29 Sep 2020 04:37:31

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:29', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0b0cecec-49f1-4ffa-808e-9ac87c6212e4' User entered '28 Sep 2020 23:37'	System	29 Sep 2020 04:37:31
	System	29 Sep 2020 04:37:31



US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:02', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '84a41bbb-36e5-4415-99d0-b916e79ad8ba' User entered 'None (1)'	System	22 Sep 2020 21:03:13
	System	22 Sep 2020 21:03:13

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:05', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '84a41bbb-36e5-4415-99d0-b916e79ad8ba' User entered 'No (N)'	System	22 Sep 2020 21:03:13
	System	22 Sep 2020 21:03:13

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '84a41bbb-36e5-4415-99d0-b916e79ad8ba' User entered 'No (N)'	System	22 Sep 2020 21:03:13
	System	22 Sep 2020 21:03:13

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:09', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '84a41bbb-36e5-4415-99d0-b916e79ad8ba' User entered 'None (1)'	System	22 Sep 2020 21:03:13
	System	22 Sep 2020 21:03:13

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '84a41bbb-36e5-4415-99d0-b916e79ad8ba' User entered '22 Sep 2020 16:03'	System	22 Sep 2020 21:03:13
	System	22 Sep 2020 21:03:13



**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '22 Sep 2020 15:50'	System	22 Sep 2020 20:35:38

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '22 Sep 2020 18:20'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'dce9fc38-0859-4c85-9045-75402d25269a' User entered 'None (1)'	System	23 Sep 2020 08:38:07
	System	23 Sep 2020 08:38:07

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:54', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'dce9fc38-0859-4c85-9045-75402d25269a' User entered 'No (N)'	System	23 Sep 2020 08:38:07
	System	23 Sep 2020 08:38:07

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:56', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'dce9fc38-0859-4c85-9045-75402d25269a' User entered 'No (N)'	System	23 Sep 2020 08:38:07
	System	23 Sep 2020 08:38:07

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:58', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'dce9fc38-0859-4c85-9045-75402d25269a' User entered 'None (1)'	System	23 Sep 2020 08:38:07
	System	23 Sep 2020 08:38:07

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:02', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'dce9fc38-0859-4c85-9045-75402d25269a' User entered '23 Sep 2020 03:38'	System	23 Sep 2020 08:38:07
	System	23 Sep 2020 08:38:07



US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '22 Sep 2020 19:15'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 2'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:27', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b8e143e-bdc6-4050-9260-4d4e51989e06'	System	24 Sep 2020 00:29:42
User entered 'None (1)'	System	24 Sep 2020 00:29:42

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b8e143e-bdc6-4050-9260-4d4e51989e06' User entered 'No (N)'	System	24 Sep 2020 00:29:42
	System	24 Sep 2020 00:29:42

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:34', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b8e143e-bdc6-4050-9260-4d4e51989e06' User entered 'No (N)'	System	24 Sep 2020 00:29:42
	System	24 Sep 2020 00:29:42

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:36', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b8e143e-bdc6-4050-9260-4d4e51989e06'	System	24 Sep 2020 00:29:42
User entered 'None (1)'	System	24 Sep 2020 00:29:42

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:38', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b8e143e-bdc6-4050-9260-4d4e51989e06' User entered '23 Sep 2020 19:29'	System	24 Sep 2020 00:29:42
	System	24 Sep 2020 00:29:42



US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 3'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:05', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fe3f32fe-ae98-4d8a-a410-ac1a518353ce' User entered 'None (1)'	System	25 Sep 2020 07:38:22
	System	25 Sep 2020 07:38:22

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:09', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fe3f32fe-ae98-4d8a-a410-ac1a518353ce' User entered 'No (N)'	System	25 Sep 2020 07:38:22
	System	25 Sep 2020 07:38:22

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:12', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fe3f32fe-ae98-4d8a-a410-ac1a518353ce' User entered 'No (N)'	System	25 Sep 2020 07:38:22
	System	25 Sep 2020 07:38:22

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:16', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fe3f32fe-ae98-4d8a-a410-ac1a518353ce' User entered 'None (1)'	System	25 Sep 2020 07:38:22
	System	25 Sep 2020 07:38:22

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fe3f32fe-ae98-4d8a-a410-ac1a518353ce' User entered '25 Sep 2020 02:38'	System	25 Sep 2020 07:38:22
	System	25 Sep 2020 07:38:22



**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 4'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:42', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'df10bfc7-d427-4478-9052-480c7caaf04c'	System	26 Sep 2020 01:46:54
User entered 'None (1)'	System	26 Sep 2020 01:46:54

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:46', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'df10bfc7-d427-4478-9052-480c7eaaf04c'	System	26 Sep 2020 01:46:54
User entered 'No (N)'	System	26 Sep 2020 01:46:54

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:48', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'df10bfc7-d427-4478-9052-480c7eaaf04c'	System	26 Sep 2020 01:46:54
User entered 'No (N)'	System	26 Sep 2020 01:46:54

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'df10bfc7-d427-4478-9052-480c7caaf04c'	System	26 Sep 2020 01:46:54
User entered 'None (1)'	System	26 Sep 2020 01:46:54

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'df10bfc7-d427-4478-9052-480c7eaaf04c' User entered '25 Sep 2020 20:46'	System	26 Sep 2020 01:46:54
	System	26 Sep 2020 01:46:54



**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 5'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:54', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c649ff59-9baf-43d9-be35-802b33173cba'	System	27 Sep 2020 04:11:09
User entered 'None (1)'	System	27 Sep 2020 04:11:09

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:57', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c649ff59-9baf-43d9-be35-802b33173cba'	System	27 Sep 2020 04:11:09
User entered 'No (N)'	System	27 Sep 2020 04:11:09

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:58', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c649ff59-9baf-43d9-be35-802b33173cba'	System	27 Sep 2020 04:11:09
User entered 'No (N)'	System	27 Sep 2020 04:11:09

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:59', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c649ff59-9baf-43d9-be35-802b33173cba'	System	27 Sep 2020 04:11:09
User entered 'None (1)'	System	27 Sep 2020 04:11:09

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c649ff59-9baf-43d9-be35-802b33173cba'	System	27 Sep 2020 04:11:09
User entered '26 Sep 2020 23:11'	System	27 Sep 2020 04:11:09



US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 6'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '08ebd9f3-e883-4925-885c-2b711db5a169'	System	28 Sep 2020 05:43:21
User entered 'None (1)'	System	28 Sep 2020 05:43:21

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '08ebd9f3-e883-4925-885c-2b711db5a169' User entered 'No (N)'	System	28 Sep 2020 05:43:21
	System	28 Sep 2020 05:43:21

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:13', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '08ebd9f3-e883-4925-885c-2b711db5a169' User entered 'No (N)'	System	28 Sep 2020 05:43:21
	System	28 Sep 2020 05:43:21

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:16', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '08ebd9f3-e883-4925-885c-2b711db5a169' User entered 'None (1)'	System	28 Sep 2020 05:43:21
	System	28 Sep 2020 05:43:21

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '08ebd9f3-e883-4925-885c-2b711db5a169' User entered '28 Sep 2020 00:43'	System	28 Sep 2020 05:43:21
	System	28 Sep 2020 05:43:21



**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:33:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 7'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:34', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8170e434-7a32-4a06-8d72-40304bcf7b45' User entered 'None (1)'	System	29 Sep 2020 04:37:48
	System	29 Sep 2020 04:37:48

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:33:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:38', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8170e434-7a32-4a06-8d72-40304bcf7b45' User entered 'No (N)'	System	29 Sep 2020 04:37:48
	System	29 Sep 2020 04:37:48

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:41', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8170e434-7a32-4a06-8d72-40304bcf7b45'	System	29 Sep 2020 04:37:48
User entered 'No (N)'	System	29 Sep 2020 04:37:48

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:33:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:43', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8170e434-7a32-4a06-8d72-40304bcf7b45'	System	29 Sep 2020 04:37:48
User entered 'None (1)'	System	29 Sep 2020 04:37:48

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:45', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8170e434-7a32-4a06-8d72-40304bcf7b45' User entered '28 Sep 2020 23:37'	System	29 Sep 2020 04:37:48
	System	29 Sep 2020 04:37:48



**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:16', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' User entered 'None (0)'	System	22 Sep 2020 21:03:31
	System	22 Sep 2020 21:03:31

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:18', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' User entered 'None (0)'	System	22 Sep 2020 21:03:31
	System	22 Sep 2020 21:03:31

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' User entered 'None (0)'	System	22 Sep 2020 21:03:31
	System	22 Sep 2020 21:03:31

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:21', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' User entered 'None (0)'	System	22 Sep 2020 21:03:31
	System	22 Sep 2020 21:03:31

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' User entered 'None (0)'	System	22 Sep 2020 21:03:31
	System	22 Sep 2020 21:03:31



US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:23', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' User entered 'None (0)'	System	22 Sep 2020 21:03:31
	System	22 Sep 2020 21:03:31

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:26', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' User entered 'No (N)'	System	22 Sep 2020 21:03:31
	System	22 Sep 2020 21:03:31

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:28', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' User entered '22 Sep 2020 16:03'	System	22 Sep 2020 21:03:31
	System	22 Sep 2020 21:03:31

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:33:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '22 Sep 2020 15:50'	System	22 Sep 2020 20:35:38

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '22 Sep 2020 18:20'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:06', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' User entered 'None (0)'	System	23 Sep 2020 08:38:24
	System	23 Sep 2020 08:38:24

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:08', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' User entered 'None (0)'	System	23 Sep 2020 08:38:24
	System	23 Sep 2020 08:38:24



US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' User entered 'None (0)'	System	23 Sep 2020 08:38:24
	System	23 Sep 2020 08:38:24

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' User entered 'None (0)'	System	23 Sep 2020 08:38:24
	System	23 Sep 2020 08:38:24

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:14', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' User entered 'None (0)'	System	23 Sep 2020 08:38:24
	System	23 Sep 2020 08:38:24

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' User entered 'None (0)'	System	23 Sep 2020 08:38:24
	System	23 Sep 2020 08:38:24

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' User entered 'No (N)'	System	23 Sep 2020 08:38:24
	System	23 Sep 2020 08:38:24

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:33:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' User entered '23 Sep 2020 03:38'	System	23 Sep 2020 08:38:24
	System	23 Sep 2020 08:38:24

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '22 Sep 2020 19:15'	System	22 Sep 2020 20:35:38

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 20:35:38



US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 2'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:43', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' User entered 'None (0)'	System	24 Sep 2020 00:30:15
	System	24 Sep 2020 00:30:15

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:44', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' User entered 'None (0)'	System	24 Sep 2020 00:30:15
	System	24 Sep 2020 00:30:15

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:46', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' User entered 'None (0)'	System	24 Sep 2020 00:30:15
	System	24 Sep 2020 00:30:15

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:49', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' User entered 'None (0)'	System	24 Sep 2020 00:30:15
	System	24 Sep 2020 00:30:15

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' User entered 'None (0)'	System	24 Sep 2020 00:30:15
	System	24 Sep 2020 00:30:15

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' User entered 'None (0)'	System	24 Sep 2020 00:30:15
	System	24 Sep 2020 00:30:15

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:30:05', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' User entered 'No (N)'	System	24 Sep 2020 00:30:15
	System	24 Sep 2020 00:30:15



**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:30:06', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' User entered '23 Sep 2020 19:30'	System	24 Sep 2020 00:30:15
	System	24 Sep 2020 00:30:15

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 3'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' User entered 'None (0)'	System	25 Sep 2020 07:38:41
	System	25 Sep 2020 07:38:41

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:23', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' User entered 'None (0)'	System	25 Sep 2020 07:38:41
	System	25 Sep 2020 07:38:41

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:25', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' User entered 'None (0)'	System	25 Sep 2020 07:38:41
	System	25 Sep 2020 07:38:41

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:26', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' User entered 'None (0)'	System	25 Sep 2020 07:38:41
	System	25 Sep 2020 07:38:41



US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:29', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' User entered 'None (0)'	System	25 Sep 2020 07:38:41
	System	25 Sep 2020 07:38:41

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:31', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737'	System	25 Sep 2020 07:38:41
User entered 'None (0)'	System	25 Sep 2020 07:38:41

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:34', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737'	System	25 Sep 2020 07:38:41
User entered 'No (N)'	System	25 Sep 2020 07:38:41

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:33:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:37', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' User entered '25 Sep 2020 02:38'	System	25 Sep 2020 07:38:41
	System	25 Sep 2020 07:38:41

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 4'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:58', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' User entered 'None (0)'	System	26 Sep 2020 01:47:17
	System	26 Sep 2020 01:47:17



US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:59', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' User entered 'None (0)'	System	26 Sep 2020 01:47:17
	System	26 Sep 2020 01:47:17

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:47:02', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' User entered 'None (0)'	System	26 Sep 2020 01:47:17
	System	26 Sep 2020 01:47:17

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:47:04', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' User entered 'None (0)'	System	26 Sep 2020 01:47:17
	System	26 Sep 2020 01:47:17

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:33:11**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:47:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' User entered 'None (0)'	System	26 Sep 2020 01:47:17
	System	26 Sep 2020 01:47:17

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:33:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:47:09', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' User entered 'None (0)'	System	26 Sep 2020 01:47:17
	System	26 Sep 2020 01:47:17

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:47:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' User entered 'No (N)'	System	26 Sep 2020 01:47:17
	System	26 Sep 2020 01:47:17

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:47:13', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' User entered '25 Sep 2020 20:47'	System	26 Sep 2020 01:47:17
	System	26 Sep 2020 01:47:17

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 20:35:38



**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 5'	System	22 Sep 2020 20:35:38

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:33:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109' User entered 'None (0)'	System	27 Sep 2020 04:11:26
	System	27 Sep 2020 04:11:26

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109'	System	27 Sep 2020 04:11:26
User entered 'None (0)'	System	27 Sep 2020 04:11:26

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:13', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109' User entered 'None (0)'	System	27 Sep 2020 04:11:26
	System	27 Sep 2020 04:11:26

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109' User entered 'None (0)'	System	27 Sep 2020 04:11:26
	System	27 Sep 2020 04:11:26

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:16', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109' User entered 'None (0)'	System	27 Sep 2020 04:11:26
	System	27 Sep 2020 04:11:26

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:33:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109' User entered 'None (0)'	System	27 Sep 2020 04:11:26
	System	27 Sep 2020 04:11:26



US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:21', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109'	System	27 Sep 2020 04:11:26
User entered 'No (N)'	System	27 Sep 2020 04:11:26

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:23', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109'	System	27 Sep 2020 04:11:26
User entered '26 Sep 2020 23:11'	System	27 Sep 2020 04:11:26

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 6'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:24', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' User entered 'None (0)'	System	28 Sep 2020 05:43:43
	System	28 Sep 2020 05:43:43

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:26', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' User entered 'None (0)'	System	28 Sep 2020 05:43:43
	System	28 Sep 2020 05:43:43

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:28', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' User entered 'None (0)'	System	28 Sep 2020 05:43:43
	System	28 Sep 2020 05:43:43



US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' User entered 'None (0)'	System	28 Sep 2020 05:43:43
	System	28 Sep 2020 05:43:43

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:31', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' User entered 'None (0)'	System	28 Sep 2020 05:43:43
	System	28 Sep 2020 05:43:43

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:33', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' User entered 'None (0)'	System	28 Sep 2020 05:43:43
	System	28 Sep 2020 05:43:43

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:36', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' User entered 'No (N)'	System	28 Sep 2020 05:43:43
	System	28 Sep 2020 05:43:43

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:40', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' User entered '28 Sep 2020 00:43'	System	28 Sep 2020 05:43:43
	System	28 Sep 2020 05:43:43

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	22 Sep 2020 20:35:38
User entered 'Day 7'	System	22 Sep 2020 20:35:38



US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:48', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' User entered 'None (0)'	System	29 Sep 2020 04:38:06
	System	29 Sep 2020 04:38:06

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:52', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' User entered 'None (0)'	System	29 Sep 2020 04:38:06
	System	29 Sep 2020 04:38:06

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' User entered 'None (0)'	System	29 Sep 2020 04:38:06
	System	29 Sep 2020 04:38:06

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:55', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' User entered 'None (0)'	System	29 Sep 2020 04:38:06
	System	29 Sep 2020 04:38:06

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:57', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' User entered 'None (0)'	System	29 Sep 2020 04:38:06
	System	29 Sep 2020 04:38:06

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:33:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:59', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' User entered 'None (0)'	System	29 Sep 2020 04:38:06
	System	29 Sep 2020 04:38:06

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:38:02', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' User entered 'No (N)'	System	29 Sep 2020 04:38:06
	System	29 Sep 2020 04:38:06

US3292320

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:33:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:38:04', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' User entered '28 Sep 2020 23:38'	System	29 Sep 2020 04:38:06
	System	29 Sep 2020 04:38:06



**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 20:35:38

**US3292320**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:33:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 20:35:38

US3292320

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:29:10
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	01 Oct 2020 13:28:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 13:28:34
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	01 Oct 2020 13:28:25
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:28:25

**US3292320**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	29 Jan 2021 18:29:10
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 13:28:25

**US3292320**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:29:10
User entered 'Contact Not Made (CONTACT NOT MADE)'		01 Oct 2020 13:28:25

US3292320

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:29:10
User entered '3 attempts made to subject, call went straight to voicemail, voicemail box full unable to lvm.'		01 Oct 2020 13:28:25

**US3292320**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 18:29:45
User entered 'Yes (Y)'		01 Oct 2020 13:28:40

**US3292320**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'l'	System	01 Oct 2020 13:28:40



**US3292320**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:30:19
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	06 Oct 2020 22:22:11

**US3292320**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:30:19
User entered '6 Oct 2020'	Kristy Trevino (b) (4)	06 Oct 2020 22:22:11

US3292320

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:30:19
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4)	06 Oct 2020 22:22:11

US3292320

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:30:19
User entered empty.	Kristy Trevino (b) (4)	06 Oct 2020 22:22:11

**US3292320**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:30:31
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	06 Oct 2020 22:22:28

**US3292320**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'l'	System	06 Oct 2020 22:22:28

**US3292320**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	29 Jan 2021 18:31:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 15:17:44

**US3292320**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:31:25
User entered '14 Oct 2020'		14 Oct 2020 15:17:44



**US3292320**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:31:25
User entered 'Contact Made (CONTACT MADE)'		14 Oct 2020 15:17:44

US3292320

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:31:25
User entered empty.		14 Oct 2020 15:17:44

**US3292320**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:31:29
User entered 'Yes (Y)'		14 Oct 2020 15:17:52

**US3292320**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'I'	System	14 Oct 2020 15:17:52

**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:32:10
User entered 'Yes (Y)'	Kevin Martinez (b) (4)	21 Oct 2020 20:53:59

**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:32:10
User entered '21 Oct 2020'	Kevin Martinez (b) (4)	21 Oct 2020 20:53:59

**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[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 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:32:10
User entered 'Clinic (Clinic)'	Kevin Martinez (b) (4)	21 Oct 2020 20:53:59

**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'VISIT3'	System	21 Oct 2020 20:53:59



**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:00
User entered 'Yes (Y)'	Kevin Martinez (b) (4)	21 Oct 2020 20:54:41

**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:00
User entered '21 Oct 2020'	Kevin Martinez (b) (4)	21 Oct 2020 20:54:41

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:33:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 20:54:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Oct 2020 20:54:51
User entered '10:50' reason for change: Data Entry Error	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:54:51
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 20:54:41
User entered empty.	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:54:41

**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered '21 Oct 2020 10:50'	System	21 Oct 2020 20:54:51
User entered empty.	System	21 Oct 2020 20:54:41

**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:00
User entered '36.6' C	Kevin Martinez (b) (4)	21 Oct 2020 20:54:41

**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:00
User entered 'Oral (Oral)'	Kevin Martinez (b) (4)	21 Oct 2020 20:54:41

**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:00
User entered empty.	Kevin Martinez (b) (4)	21 Oct 2020 20:54:41

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:00
User entered '90'	Kevin Martinez (b) (4)	21 Oct 2020 20:54:41



US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'bpm'	System	21 Oct 2020 20:54:41

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:00
User entered '16'	Kevin Martinez (b) (4)	21 Oct 2020 20:54:41

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'breaths/min'	System	21 Oct 2020 20:54:41

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:00
User entered '151'	Kevin Martinez (b) (4)	21 Oct 2020 20:54:41

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'mmHg'	System	21 Oct 2020 20:54:41

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:00
User entered '89'	Kevin Martinez (b) (4)	21 Oct 2020 20:54:41

**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'mmHg'	System	21 Oct 2020 20:54:41

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07



**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

**Weight (derived)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07

US3292320

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:33:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:23
User entered 'No (N)'	Kevin Martinez (b) (4)	21 Oct 2020 20:54:55

US3292320

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:33:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:23
User entered empty.	Kevin Martinez (b) (4)	21 Oct 2020 20:54:55

US3292320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:33:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:38
User entered 'Yes (Y)'	Kevin Martinez (b) (4)	21 Oct 2020 20:55:08

US3292320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:33:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:38
User entered '21 Oct 2020'	Kevin Martinez (b) (4)	21 Oct 2020 20:55:08

**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:33:11**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:38
User entered '11:07'	Kevin Martinez (b) (4)	21 Oct 2020 20:55:08

US3292320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:33:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered '21 Oct 2020 11:07'	System	21 Oct 2020 20:55:08

US3292320

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:33:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:33:43
User entered 'Yes (Y)'	Kevin Martinez (b) (4)	21 Oct 2020 20:55:14



**US3292320**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'I'	System	21 Oct 2020 20:55:14

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 64'	System	25 Aug 2020 21:40:04

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

[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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-10-26T09:29:06', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c62edd49-fce5-4683-9981-51895e27e8a2'	System	26 Oct 2020 14:29:18
User entered 'No (N)'	System	26 Oct 2020 14:29:18

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

Have you been exposed to someone with 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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-10-26T09:29:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c62edd49-fce5-4683-9981-51895e27e8a2'	System	26 Oct 2020 14:29:18
User entered 'No (N)'	System	26 Oct 2020 14:29:18

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-10-26T09:29:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c62edd49-fce5-4683-9981-51895e27e8a2' User entered '26 Oct 2020 09:29:15'	System	26 Oct 2020 14:29:18
	System	26 Oct 2020 14:29:18

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 21:40:04

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 71'	System	25 Aug 2020 21:40:04



US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

[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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-01T04:15:12', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5cfd6884-86c4-4f8b-aaf0-f15ff0f050db'	System	01 Nov 2020 10:15:30
User entered 'No (N)'	System	01 Nov 2020 10:15:30

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

Have you been exposed to someone with 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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-01T04:15:18', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5cfd6884-86c4-4f8b-aaf0-f15ff0f050db'	System	01 Nov 2020 10:15:30
User entered 'No (N)'	System	01 Nov 2020 10:15:30

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-01T04:15:25', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5cfd6884-86c4-4f8b-aaf0-f15ff0f050db' User entered '01 Nov 2020 04:15:25'	System	01 Nov 2020 10:15:30
	System	01 Nov 2020 10:15:30

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 21:40:04

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 21:40:04

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered 'Day 78'	System	25 Aug 2020 21:40:04

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

[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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-09T10:09:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '762078ce-0f2d-4144-84b7-94d8a8f7fc5b'	System	09 Nov 2020 16:11:48
User entered 'No (N)'	System	09 Nov 2020 16:11:48

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:33:11

Have you been exposed to someone with 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)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-09T10:11:37', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '762078ce-0f2d-4144-84b7-94d8a8f7fc5b'	System	09 Nov 2020 16:11:48
User entered 'No (N)'	System	09 Nov 2020 16:11:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-09T10:11:45', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '762078ce-0f2d-4144-84b7-94d8a8f7fc5b' User entered '09 Nov 2020 10:11:45'	System	09 Nov 2020 16:11:48
	System	09 Nov 2020 16:11:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 21:40:04

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:56
Data entry locked.	System	25 Aug 2020 21:40:04
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 21:40:04

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-22T00:20:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cbd4eefd-86be-4ec7-bdb9-f80fb21067b0' User entered 'No (N)'	System	22 Nov 2020 06:20:54
	System	22 Nov 2020 06:20:54

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-22T00:20:25', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cbd4eefd-86be-4ec7-bdb9-f80fb21067b0' User entered 'No (N)'	System	22 Nov 2020 06:20:54

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-22T00:20:49', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cbd4eefd-86be-4ec7-bdb9-f80fb21067b0' User entered '22 Nov 2020 00:20:49'	System	22 Nov 2020 06:20:54
	System	22 Nov 2020 06:20:54

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-26T00:07:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'bc0cf202-cf1a-419a-ab8e-b93e461a2abd' User entered 'No (N)'	System	26 Nov 2020 06:07:25

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-26T00:07:18', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'bc0cf202-cf1a-419a-ab8e-b93e461a2abd' User entered 'No (N)'	System	26 Nov 2020 06:07:25

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-26T00:07:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'bc0cf202-cf1a-419a-ab8e-b93e461a2abd' User entered '26 Nov 2020 00:07:22'	System	26 Nov 2020 06:07:25
	System	26 Nov 2020 06:07:25

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-12-03T00:01:43', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd04d9bd8-5109-4cdf-948d-f7cf9ca4660d' User entered 'No (N)'	System	03 Dec 2020 06:02:11
	System	03 Dec 2020 06:02:11

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-12-03T00:01:50', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd04d9bd8-5109-4cdf-948d-f7cf9ca4660d' User entered 'No (N)'	System	03 Dec 2020 06:02:11
	System	03 Dec 2020 06:02:11

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-12-03T00:01:54', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd04d9bd8-5109-4cdf-948d-f7cf9ca4660d' User entered '03 Dec 2020 00:01:54'	System	03 Dec 2020 06:02:11
	System	03 Dec 2020 06:02:11

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-12-10T20:52:37', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '42f13066-3c71-46ba-b614-d617f8900101' User entered 'No (N)'	System	11 Dec 2020 02:52:52
	System	11 Dec 2020 02:52:52

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-12-10T20:52:45', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '42f13066-3c71-46ba-b614-d617f8900101' User entered 'No (N)'	System	11 Dec 2020 02:52:52
	System	11 Dec 2020 02:52:52



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-12-10T20:52:49', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '42f13066-3c71-46ba-b614-d617f8900101' User entered '10 Dec 2020 20:52:49'	System	11 Dec 2020 02:52:52
	System	11 Dec 2020 02:52:52

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-12-17T00:02:04', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '54041547-7996-4edd-b553-06d7dfdf9a24' User entered 'No (N)'	System	17 Dec 2020 06:02:26
	System	17 Dec 2020 06:02:26

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-12-17T00:02:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '54041547-7996-4edd-b553-06d7dfdf9a24' User entered 'No (N)'	System	17 Dec 2020 06:02:26
	System	17 Dec 2020 06:02:26

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-12-17T00:02:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '54041547-7996-4edd-b553-06d7dfdf9a24' User entered '17 Dec 2020 00:02:10'	System	17 Dec 2020 06:02:26
	System	17 Dec 2020 06:02:26

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-12-24T01:58:28', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'ee4150b0-e3b6-4e2e-b7c4-d4b0c145b7b2' User entered 'No (N)'	System	24 Dec 2020 07:59:08
	System	24 Dec 2020 07:59:08

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-12-24T01:59:01', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'ee4150b0-e3b6-4e2e-b7c4-d4b0c145b7b2' User entered 'No (N)'	System	24 Dec 2020 07:59:08
	System	24 Dec 2020 07:59:08

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-12-24T01:59:04', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'ee4150b0-e3b6-4e2e-b7c4-d4b0c145b7b2' User entered '24 Dec 2020 01:59:04'	System	24 Dec 2020 07:59:08
	System	24 Dec 2020 07:59:08

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-02T12:05:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '464e44a6-d894-418f-b41b-916c31a2727e' User entered 'No (N)'	System	02 Jan 2021 18:05:30
	System	02 Jan 2021 18:05:30

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-02T12:05:24', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '464e44a6-d894-418f-b41b-916c31a2727e' User entered 'No (N)'	System	02 Jan 2021 18:05:30
	System	02 Jan 2021 18:05:30

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-02T12:05:27', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '464e44a6-d894-418f-b41b-916c31a2727e' User entered '02 Jan 2021 12:05:27'	System	02 Jan 2021 18:05:30
	System	02 Jan 2021 18:05:30

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-10T02:15:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '4a2a7856-fdb6-4f08-aad7-4c61a430a33b' User entered 'No (N)'	System	10 Jan 2021 08:15:24
	System	10 Jan 2021 08:15:24

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-10T02:15:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '4a2a7856-fdb6-4f08-aad7-4c61a430a33b' User entered 'No (N)'	System	10 Jan 2021 08:15:24
	System	10 Jan 2021 08:15:24



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-10T02:15:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '4a2a7856-fdb6-4f08-aad7-4c61a430a33b' User entered '10 Jan 2021 02:15:22'	System	10 Jan 2021 08:15:24
	System	10 Jan 2021 08:15:24

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-14T06:53:37', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c7afb18d-93c8-459f-8483-05f6d8c1e657'	System	14 Jan 2021 12:55:16
User entered 'Yes (Y)'	System	14 Jan 2021 12:55:16

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-14T06:54:33', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c7afb18d-93c8-459f-8483-05f6d8c1e657'	System	14 Jan 2021 12:55:16
User entered 'No (N)'	System	14 Jan 2021 12:55:16

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-14T06:54:45', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c7afb18d-93c8-459f-8483-05f6d8c1e657'	System	14 Jan 2021 12:55:16
User entered 'No (N)'	System	14 Jan 2021 12:55:16

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-14T06:55:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c7afb18d-93c8-459f-8483-05f6d8c1e657'	System	14 Jan 2021 12:55:16
User entered 'No (N)'	System	14 Jan 2021 12:55:16



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-14T06:55:12', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c7afb18d-93c8-459f-8483-05f6d8c1e657'	System	14 Jan 2021 12:55:16
User entered '14 Jan 2021 06:55:12'	System	14 Jan 2021 12:55:16

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-21T00:16:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d73a90c-5820-441e-9414-991f5d5aa0f4' User entered 'No (N)'	System	21 Jan 2021 06:16:19
	System	21 Jan 2021 06:16:19

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-21T00:16:13', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d73a90c-5820-441e-9414-991f5d5aa0f4' User entered 'No (N)'	System	21 Jan 2021 06:16:19
	System	21 Jan 2021 06:16:19

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-01-21T00:16:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d73a90c-5820-441e-9414-991f5d5aa0f4' User entered '21 Jan 2021 00:16:17'	System	21 Jan 2021 06:16:19
	System	21 Jan 2021 06:16:19

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-01T21:50:57', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07cbf031-b162-4c3b-bc30-9f16b57cef1b' User entered 'No (N)'	System	02 Feb 2021 03:51:08
	System	02 Feb 2021 03:51:08

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-01T21:51:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07cbf031-b162-4c3b-bc30-9f16b57cef1b' User entered 'No (N)'	System	02 Feb 2021 03:51:08
	System	02 Feb 2021 03:51:08

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-01T21:51:03', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07cbf031-b162-4c3b-bc30-9f16b57cef1b' User entered '01 Feb 2021 21:51:03'	System	02 Feb 2021 03:51:08
	System	02 Feb 2021 03:51:08

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-06T12:02:32', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '924cb938-b163-4c58-94a7-b7ddc0d27972'	System	06 Feb 2021 18:04:59
User entered 'No (N)'	System	06 Feb 2021 18:04:59

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-06T12:02:36', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '924cb938-b163-4c58-94a7-b7ddc0d27972'	System	06 Feb 2021 18:04:59
User entered 'No (N)'	System	06 Feb 2021 18:04:59

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-06T12:02:39', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '924cb938-b163-4c58-94a7-b7ddc0d27972'	System	06 Feb 2021 18:04:59
User entered '06 Feb 2021 12:02:39'	System	06 Feb 2021 18:04:59

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-11T00:03:32', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '502363d3-fa78-4af4-8b81-7d5368ebf0b6' User entered 'No (N)'	System	11 Feb 2021 06:03:40
	System	11 Feb 2021 06:03:40

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-11T00:03:34', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '502363d3-fa78-4af4-8b81-7d5368ebf0b6' User entered 'No (N)'	System	11 Feb 2021 06:03:40
	System	11 Feb 2021 06:03:40



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-11T00:03:38', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '502363d3-fa78-4af4-8b81-7d5368ebf0b6' User entered '11 Feb 2021 00:03:38'	System	11 Feb 2021 06:03:40
	System	11 Feb 2021 06:03:40

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-18T00:54:12', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8431b847-7c6c-4c33-b156-9a1811cfad42' User entered 'No (N)'	System	18 Feb 2021 06:54:20
	System	18 Feb 2021 06:54:20

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-18T00:54:14', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8431b847-7c6c-4c33-b156-9a1811cfad42'	System	18 Feb 2021 06:54:20
User entered 'No (N)'	System	18 Feb 2021 06:54:20

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-18T00:54:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8431b847-7c6c-4c33-b156-9a1811cfad42' User entered '18 Feb 2021 00:54:17'	System	18 Feb 2021 06:54:20
	System	18 Feb 2021 06:54:20

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-26T00:31:39-06:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '71de5608-4f4b-4c26-93d7-03ba22dc4d7c' User entered 'No (N)'	System	26 Feb 2021 06:31:48
	System	26 Feb 2021 06:31:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-26T00:31:41-06:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '71de5608-4f4b-4c26-93d7-03ba22dc4d7c' User entered 'No (N)'	System	26 Feb 2021 06:31:48
	System	26 Feb 2021 06:31:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-26T00:31:45-06:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '71de5608-4f4b-4c26-93d7-03ba22dc4d7c' User entered '26 Feb 2021 06:31:45'	System	26 Feb 2021 06:31:48
	System	26 Feb 2021 06:31:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-03-06T13:01:49-06:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c1d6e285-a7f6-46e2-bb3e-9b78d4bc77f9'	System	06 Mar 2021 19:01:59
User entered 'No (N)'	System	06 Mar 2021 19:01:59

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-03-06T13:01:52-06:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c1d6e285-a7f6-46e2-bb3e-9b78d4bc77f9'	System	06 Mar 2021 19:01:59
User entered 'No (N)'	System	06 Mar 2021 19:01:59

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-03-06T13:01:54-06:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c1d6e285-a7f6-46e2-bb3e-9b78d4bc77f9' User entered '06 Mar 2021 13:01:54'	System	06 Mar 2021 19:01:59
	System	06 Mar 2021 19:01:59

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-03-11T04:03:22-06:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd1ded2da-a57e-4571-8026-6a0dacb07d62'	System	11 Mar 2021 10:03:42
User entered 'No (N)'	System	11 Mar 2021 10:03:42

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-03-11T04:03:35-06:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd1ded2da-a57e-4571-8026-6a0dacb07d62'	System	11 Mar 2021 10:03:42
User entered 'No (N)'	System	11 Mar 2021 10:03:42



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-03-11T04:03:40-06:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd1ded2da-a57e-4571-8026-6a0dacb07d62' User entered '11 Mar 2021 04:03:40'	System	11 Mar 2021 10:03:42
	System	11 Mar 2021 10:03:42

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-03-18T15:09:28-04:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '2d4db4f5-6008-45ab-8511-cebbb805f817'	System	18 Mar 2021 19:09:38
User entered 'No (N)'	System	18 Mar 2021 19:09:38

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-03-18T15:09:33-04:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '2d4db4f5-6008-45ab-8511-eebbb805f817'	System	18 Mar 2021 19:09:38
User entered 'No (N)'	System	18 Mar 2021 19:09:38

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-03-18T15:09:35-04:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '2d4db4f5-6008-45ab-8511-cebbb805f817'	System	18 Mar 2021 19:09:38
User entered '18 Mar 2021 15:09:35'	System	18 Mar 2021 19:09:38

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-03-26T10:40:35-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd76b3de6-fabf-40c9-8c83-3be988f0b217'	System	26 Mar 2021 15:40:45
User entered 'No (N)'	System	26 Mar 2021 15:40:45

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-03-26T10:40:40-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd76b3de6-fabf-40c9-8c83-3be988f0b217'	System	26 Mar 2021 15:40:45
User entered 'No (N)'	System	26 Mar 2021 15:40:45

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-03-26T10:40:43-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd76b3de6-fabf-40c9-8c83-3be988f0b217'	System	26 Mar 2021 15:40:45
User entered '26 Mar 2021 10:40:43'	System	26 Mar 2021 15:40:45

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-03T12:00:15-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'b1530b90-98b9-4907-b3ac-fd75f893e106'	System	03 Apr 2021 17:00:27
User entered 'No (N)'	System	03 Apr 2021 17:00:27

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-03T12:00:21-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'b1530b90-98b9-4907-b3ac-fd75f893e106'	System	03 Apr 2021 17:00:27
User entered 'No (N)'	System	03 Apr 2021 17:00:27

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-03T12:00:24-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'b1530b90-98b9-4907-b3ac-fd75f893e106'	System	03 Apr 2021 17:00:27
User entered '03 Apr 2021 12:00:24'	System	03 Apr 2021 17:00:27

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-11T12:05:33-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4b8166f-32ef-482e-82fc-e809ae5e8a38'	System	11 Apr 2021 17:06:29
User entered 'No (N)'	System	11 Apr 2021 17:06:29

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-11T12:05:38-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4b8166f-32ef-482e-82fc-e809ae5e8a38'	System	11 Apr 2021 17:06:29
User entered 'No (N)'	System	11 Apr 2021 17:06:29



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-11T12:05:40-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4b8166f-32ef-482e-82fc-e809ae5e8a38'	System	11 Apr 2021 17:06:29
User entered '11 Apr 2021 12:05:40'	System	11 Apr 2021 17:06:29

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-15T23:59:52-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '87807685-69ad-47b5-810c-246d14fcac2a' User entered 'No (N)'	System	16 Apr 2021 05:00:03
	System	16 Apr 2021 05:00:03

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-15T23:59:54-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '87807685-69ad-47b5-810c-246d14fcac2a' User entered 'No (N)'	System	16 Apr 2021 05:00:03
	System	16 Apr 2021 05:00:03

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-15T23:59:56-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '87807685-69ad-47b5-810c-246d14fcac2a' User entered '15 Apr 2021 23:59:56'	System	16 Apr 2021 05:00:03
	System	16 Apr 2021 05:00:03

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-25T13:43:15-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8f88830f-760d-41e7-8a0d-d9479216ed28'	System	26 Apr 2021 16:53:37
User entered 'No (N)'	System	26 Apr 2021 16:53:37

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-25T13:43:17-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8f88830f-760d-41e7-8a0d-d9479216ed28'	System	26 Apr 2021 16:53:37
User entered 'No (N)'	System	26 Apr 2021 16:53:37

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-25T13:43:19-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8f88830f-760d-41e7-8a0d-d9479216ed28'	System	26 Apr 2021 16:53:37
User entered '25 Apr 2021 13:43:19'	System	26 Apr 2021 16:53:37

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-30T14:34:23-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '25b71576-6f69-4050-90cc-dee9314c0613' User entered 'No (N)'	System	30 Apr 2021 19:34:30
	System	30 Apr 2021 19:34:30

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-30T14:34:25-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '25b71576-6f69-4050-90cc-dee9314c0613' User entered 'No (N)'	System	30 Apr 2021 19:34:30
	System	30 Apr 2021 19:34:30

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-04-30T14:34:27-05:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '25b71576-6f69-4050-90cc-dee9314c0613' User entered '30 Apr 2021 14:34:27'	System	30 Apr 2021 19:34:30
	System	30 Apr 2021 19:34:30

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 17:45:48



**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:45:48

**US3292320**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 17:45:48



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:45:48



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 17:45:48

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 17:45:48



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:45:48



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 17:45:48



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 17:45:48

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:45:48



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 17:45:48

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 17:45:48



**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 17:45:48

**US3292320**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:33:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:45:48
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 17:45:48

US3292320

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:33:11**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:07:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-28T21:45:27-06:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '20aa1d12-ff6d-4dac-96bc-d5cd8c1ae9f3'	System	03 Mar 2021 07:31:15
User entered 'No (N)'	System	03 Mar 2021 07:31:15



**US3292320**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:07:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2021-02-28T21:45:50-06:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '20aa1d12-ff6d-4dac-96bc-d5cd8c1ae9f3'	System	03 Mar 2021 07:31:15
User entered '01 Mar 2021 03:45:50'	System	03 Mar 2021 07:31:15

US3292320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		16 Mar 2021 14:11:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 22:37:58

US3292320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		16 Mar 2021 14:11:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '17 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 22:37:58

**US3292320**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:11:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 22:37:58

US3292320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:11:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 22:37:58

US3292320

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:33:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
DataPoint Verified.		16 Mar 2021 14:11:41
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 22:38:03

**US3292320**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:07
User entered 'l'	System	19 Nov 2020 22:38:03

US3292320

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:12:45
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Dec 2020 17:09:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Dec 2020 17:09:45
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	27 Dec 2020 17:09:45
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 16:34:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 16:34:49
User entered 'Yes (Y)'		03 Dec 2020 16:34:25



US3292320

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:12:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '25 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	27 Dec 2020 17:09:45
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	03 Dec 2020 16:34:49
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	03 Dec 2020 16:34:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 16:34:49
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	03 Dec 2020 16:34:25
User entered '2 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 16:34:25

US3292320

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:12:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	(b) (4)
reason for change: Data Entry Error	(b) (4), (b) (6)	27 Dec 2020 17:09:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 16:35:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Dec 2020 16:34:25

**US3292320**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:12:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:34:25

US3292320

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:33:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.		16 Mar 2021 14:13:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:27:45

**US3292320**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
User entered 'l'	System	16 Dec 2020 15:27:45

**US3292320**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.		16 Mar 2021 14:23:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Jan 2021 18:55:40

**US3292320**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.		16 Mar 2021 14:23:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '20 Jan 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Jan 2021 18:55:40

**US3292320**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.		16 Mar 2021 14:23:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Jan 2021 18:55:40



**US3292320**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:23:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Jan 2021 18:55:40

US3292320

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:33:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.		16 Mar 2021 14:23:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Jan 2021 18:55:44

**US3292320**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
User entered 'l'	System	25 Jan 2021 18:55:44

**US3292320**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.		16 Mar 2021 14:24:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:17:23

US3292320

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.		16 Mar 2021 14:24:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '17 Feb 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:17:23

**US3292320**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.		16 Mar 2021 14:24:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:17:23

US3292320

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.		16 Mar 2021 14:24:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:17:23

US3292320

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:33:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
DataPoint Verified.		16 Mar 2021 14:24:41
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:17:29



**US3292320**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:49
User entered 'l'	System	17 Feb 2021 18:17:29

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:56:59
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:29:51

US3292320

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:56:59
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	07 Apr 2021 11:47:05
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Correct as is, date OOW. ' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 17:30:10
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	06 Apr 2021 17:29:51
User entered '6 Apr 2021'	(b) (4), (b) (6)	06 Apr 2021 17:29:51

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:56:59
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Apr 2021 17:29:51

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	06 Apr 2021 17:29:51

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:57:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered 'No (N)'	(b) (4), (b) (6)	06 Apr 2021 17:30:23

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:57:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 17:30:23

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:57:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 17:30:23



**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:30:23

US3292320

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:57:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 17:30:23

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:57:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 17:30:23

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:57:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 17:30:23

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:57:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 17:30:23

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:30:23

US3292320

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:57:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:30:23

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:30:23



US3292320

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:57:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 17:30:23

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:30:23

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:57:34
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 17:30:23

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:30:23

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:33:11**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:57:47
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered 'No (N)'	(b) (4), (b) (6)	06 Apr 2021 17:30:30

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:33:11**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:57:47
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:30:30

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:33:11**

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:58:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 17:31:30

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:33:11**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:58:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered '6 Apr 2021'	(b) (4), (b) (6)	06 Apr 2021 17:31:30



**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:33:11**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:58:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered '10:42'	(b) (4), (b) (6)	06 Apr 2021 17:31:30

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:33:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '6 Apr 2021 10:42'	System	06 Apr 2021 17:31:30

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:58:36
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 17:31:55

**US3292320**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 17:31:55

**US3292320**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:49:35

**US3292320**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:04
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:49:35

**US3292320**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:33:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:49:35

US3292320

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:33:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:04
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:49:35



**US3292320**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:49:38

**US3292320**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	22 Apr 2021 20:49:38

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 16:33:11**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:44:31
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '17 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:20:18

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:33:11

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:52
DataPoint Verified.		13 Apr 2021 20:44:31
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '16:04'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:20:18

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 16:33:11**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:52
User entered '17 Nov 2020 16:04'	System	20 Nov 2020 15:20:18

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 16:33:11**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:52
DataPoint Verified.		13 Apr 2021 20:44:31
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Safety Call (Safety Call)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:20:18

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 16:33:11**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:52
DataPoint Verified.		13 Apr 2021 20:44:31
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:20:18

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Please revisit symptom log entries as Symptom Day 1 equals the first date of subject experienced symptoms. There should be one entry per Symptom Day and Date. Entries should be captured for a minimum of 14 days or until symptoms resolve, whichever is longer from the date of illness visit day 1. All symptoms should be addressed for each Symptom Day. If a temperature or oxygen saturation was not collected on a Symptom Day, the reading should be captured as ND- Not Done. If no symptoms were assessed for a given symptom day, the assessment not done box should be ticked. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:23:27
Query 'Please revisit symptom log entries as Symptom Day 1 equals the first date of subject experienced symptoms. There should be one entry per Symptom Day and Date. Entries should be captured for a minimum of 14 days or until symptoms resolve, whichever is longer from the date of illness visit day 1. All symptoms should be addressed for each Symptom Day. If a temperature or oxygen saturation was not collected on a Symptom Day, the reading should be captured as ND- Not Done. If no symptoms were assessed for a given symptom day, the assessment not done box should be ticked. ' answered with 'Updated' (Site from CRA).	Nathan Cortez (b) (4)	31 Dec 2020 19:01:02



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
User opened query 'Please revisit symptom log entries as Symptom Day 1 equals the first date of subject experienced symptoms. There should be one entry per Symptom Day and Date. Entries should be captured for a minimum of 14 days or until symptoms resolve, whichever is longer from the date of illness visit day 1. All symptoms should be addressed for each Symptom Day. If a temperature or oxygen saturation was not collected on a Symptom Day, the reading should be captured as ND- Not Done. If no symptoms were assessed for a given symptom day, the assessment not done box should be ticked. ' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 00:09:51
User entered 'Day 1 (Day 1)'	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '15 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 16:32:46
DataPoint Un-verified.	Gerardo Pena (b) (4)	21 Apr 2021 14:18:37
	(b) (4)	
Signature has been broken.	Gerardo Pena (b) (4)	21 Apr 2021 14:18:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Gerardo Pena (b) (4)	21 Apr 2021 14:18:37
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:26:29
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 01:07:01
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 01:07:01
User entered '98' reason for change: Data Entry	(b) (4), (b) (6)	14 Apr 2021 01:07:01
Error		
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered missing code ND - Not Done; reason for	Nathan Cortez (b) (4)	31 Dec 2020 18:59:53
change Data Entry Error		
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	31 Dec 2020 18:59:53
User entered empty.	System	20 Nov 2020 15:33:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:33:11

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	21 Apr 2021 16:32:47
User closed query 'Value under 38.0. Please confirm whether this constitutes as a fever.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:32:43
Query 'Value under 38.0. Please confirm whether this constitutes as a fever.' answered with 'updated' (Site from CRA).	Gerardo Pena (b) (4)	21 Apr 2021 14:19:14
DataPoint Un-verified.	(b) (4)	21 Apr 2021 14:18:37
Signature has been broken.	Gerardo Pena (b) (4)	21 Apr 2021 14:18:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Apr 2021 14:18:37
User opened query 'Value under 38.0. Please confirm whether this constitutes as a fever.' (Site from CRA).	Gerardo Pena (b) (4)	21 Apr 2021 14:18:37
User closed query 'Per source, subject reported fever. Please review and reconcile. ' (Site from CRA).	(b) (4)	19 Apr 2021 16:14:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:26:24
User signature succeeded.	(b) (4)	16 Apr 2021 21:26:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User entered '36.8' C reason for change: Data Entry Error	(b) (4)	14 Apr 2021 01:09:57
Query 'Per source, subject reported fever. Please review and reconcile. ' answered with 'Updated ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 01:09:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 01:08:11
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 01:07:01
User entered '36.83' (non-conformant).	(b) (4), (b) (6)	14 Apr 2021 01:07:01
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 01:07:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:08
	(b) (4), (b) (6)	13 Apr 2021 20:51:58

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
User opened query 'Per source, subject reported fever. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:50:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	31 Dec 2020 18:59:53
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:33:42



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Per CDM: It appears that multiple values for Day1 - Day 3 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4)	
Query 'Per CDM: It appears that multiple values for Day1 - Day 3 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' answered with 'COMPLETED' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:02:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:00:05
User opened query 'Per CDM: It appears that multiple values for Day1 - Day 3 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 09:03:01
	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

US3292320

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Form: Symptom Log (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

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Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

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Form: Symptom Log (1)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User closed query 'Per progress note dated 17Nov2020, Subject reported Mild body aches. Please review and reconcile. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:26:15
User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 21:26:13
Query 'Per progress note dated 17Nov2020, Subject reported Mild body aches. Please review and reconcile. ' answered with 'Updated ' (Site from CRA).	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	(b) (4), (b) (6)
User entered 'Mild (Mild)' reason for change: Data Entry Error		14 Apr 2021 01:08:46
DataPoint Un-verified.		14 Apr 2021 01:07:01
DataPoint Verified.		14 Apr 2021 01:07:01
User opened query 'Per progress note dated 17Nov2020, Subject reported Mild body aches. Please review and reconcile. ' (Site from CRA).		13 Apr 2021 20:52:10
User signature succeeded.		13 Apr 2021 20:51:58
User entered 'Moderate (Moderate)'	Douglas Denham (b) (4)	13 Apr 2021 20:48:20
	(b) (4)	23 Feb 2021 14:14:16
	Nathan Cortez (b) (4)	(b) (4)
		20 Nov 2020 15:33:42

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Form: Symptom Log (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:48:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

US3292320

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Form: Symptom Log (1)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42



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Form: Symptom Log (1)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

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Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

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Form: Symptom Log (1)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:51:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:33:42

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 2 (Day 2)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:35:16



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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:06:44
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
User entered '16 Nov 2020'	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Form: Symptom Log (2)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:06:52
DataPoint Un-verified.		16 Apr 2021 21:28:32
DataPoint Verified.		13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User closed query 'Value not present in source. please reconcile or clarify.' (Site from CRA).	(b) (4)	21 Apr 2021 16:32:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:32:54
Query 'Value not present in source. please reconcile or clarify.' answered with 'updated' (Site from CRA).	Gerardo Pena (b) (4)	21 Apr 2021 14:19:39
Signature has been broken.	(b) (4)	21 Apr 2021 14:19:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Gerardo Pena (b) (4)	21 Apr 2021 14:19:27
User opened query 'Value not present in source. please reconcile or clarify.' (Site from CRA).	(b) (4)	19 Apr 2021 16:13:02
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:26:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
DataPoint Un-verified.	(b) (4)	14 Apr 2021 01:11:48
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 01:11:48
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 01:11:48
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	31 Dec 2020 18:59:53
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	31 Dec 2020 18:59:53
User entered empty.	System	20 Nov 2020 15:35:16

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:33:11

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User closed query 'Value under 38.0. Please confirm if this constitutes as a fever.' (Site from CRA).	(b) (4)	21 Apr 2021 16:32:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:32:57
Query 'Value under 38.0. Please confirm if this constitutes as a fever.' answered with 'updated' (Site from CRA).	Gerardo Pena (b) (4)	21 Apr 2021 14:19:41
Signature has been broken.	(b) (4)	21 Apr 2021 14:19:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Gerardo Pena (b) (4)	21 Apr 2021 14:19:27
User opened query 'Value under 38.0. Please confirm if this constitutes as a fever.' (Site from CRA).	(b) (4)	19 Apr 2021 16:14:40
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 16:13:13
DataPoint Verified.		19 Apr 2021 16:13:07
DataPoint Un-verified.		16 Apr 2021 21:28:32
User closed query 'Per source, subject reported fever. Please review and reconcile.' (Site from CRA).		16 Apr 2021 21:26:45
DataPoint Verified.		16 Apr 2021 21:26:42
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Query 'Per source, subject reported fever. Please review and reconcile.' answered with 'UPDATED' (Site from CRA).	(b) (4)	14 Apr 2021 01:12:03
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 01:11:48
User entered '37.5' C reason for change: Data Entry Error		14 Apr 2021 01:11:48
DataPoint Un-verified.		13 Apr 2021 20:52:14
DataPoint Verified.		13 Apr 2021 20:52:01
User opened query 'Per source, subject reported fever. Please review and reconcile.' (Site from CRA)		13 Apr 2021 20:51:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	

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[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 18:59:53
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Form: Symptom Log (2)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:07:04
DataPoint Un-verified.		16 Apr 2021 21:28:32
DataPoint Verified.		13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:07:10
DataPoint Un-verified.		16 Apr 2021 21:28:32
DataPoint Verified.		13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16



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Form: Symptom Log (2)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:14:45
DataPoint Un-verified.		16 Apr 2021 21:28:32
DataPoint Verified.		13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:07:13
DataPoint Un-verified.		16 Apr 2021 21:28:32
DataPoint Verified.		13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:14:44
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Form: Symptom Log (2)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:14:47
DataPoint Un-verified.		16 Apr 2021 21:28:32
DataPoint Verified.		13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:33:11

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User closed query 'Per progress note dated 17Nov2020, subject experienced mild body aches. please review and reconcile.' (Site from CRA). DataPoint Verified.		19 Apr 2021 16:04:36
DataPoint Un-verified.		19 Apr 2021 16:04:34
DataPoint Verified.		16 Apr 2021 21:28:32
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Query 'Per progress note dated 17Nov2020, subject experienced mild body aches. please review and reconcile.' answered with 'Updated ' (Site from CRA). Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 01:12:20
User entered 'Mild (Mild)' reason for change: Data Entry Error DataPoint Un-verified.		14 Apr 2021 01:11:48
DataPoint Verified.		14 Apr 2021 01:11:48
User opened query 'Per progress note dated 17Nov2020, subject experienced mild body aches. please review and reconcile.' (Site from CRA). User signature succeeded.		13 Apr 2021 20:52:17
User entered 'Moderate (Moderate)'	Douglas Denham (b) (4)	13 Apr 2021 20:52:01
	(b) (4)	13 Apr 2021 20:49:14
	Nathan Cortez (b) (4)	23 Feb 2021 14:14:16
		20 Nov 2020 15:35:16

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:07:07
DataPoint Un-verified.		16 Apr 2021 21:28:32
DataPoint Verified.		13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:15:54
DataPoint Un-verified.		16 Apr 2021 21:28:32
DataPoint Verified.		13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:15:55
DataPoint Un-verified.		16 Apr 2021 21:28:32
DataPoint Verified.		13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16



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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:15:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Form: Symptom Log (2)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:15:58
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:16:00
DataPoint Un-verified.		16 Apr 2021 21:28:32
DataPoint Verified.		13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:16:02
DataPoint Un-verified.		16 Apr 2021 21:28:32
DataPoint Verified.		13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:16:04
DataPoint Un-verified.		16 Apr 2021 21:28:32
DataPoint Verified.		13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:16:06
DataPoint Un-verified.		16 Apr 2021 21:28:32
DataPoint Verified.		13 Apr 2021 20:52:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 19:55:47
User entered empty.	(b) (4), (b) (6)	
	Nathan Cortez (b) (4)	20 Nov 2020 15:35:16

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 3 (Day 3)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '17 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:35:38



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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User closed query 'Value not present in source. please reconcile or clarify.' (Site from CRA).	(b) (4)	21 Apr 2021 16:33:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:33:04
Query 'Value not present in source. please reconcile or clarify.' answered with 'updated' (Site from CRA).	Gerardo Pena (b) (4)	21 Apr 2021 14:20:12
DataPoint Un-verified.	(b) (4)	21 Apr 2021 14:20:07
Signature has been broken.	Gerardo Pena (b) (4)	21 Apr 2021 14:20:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Gerardo Pena (b) (4)	21 Apr 2021 14:20:07
User opened query 'Value not present in source. please reconcile or clarify.' (Site from CRA).	(b) (4)	21 Apr 2021 14:20:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:12:37
	(b) (4)	16 Apr 2021 21:27:27
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
DataPoint Un-verified.	(b) (4)	14 Apr 2021 01:13:30
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 01:13:30
User entered '97' reason for change: Data Entry Error	(b) (4)	14 Apr 2021 01:13:30
DataPoint Verified.	(b) (4)	13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	31 Dec 2020 18:59:53
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	31 Dec 2020 18:59:53
User entered empty.	System	20 Nov 2020 15:35:38

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 16:33:08
DataPoint Un-verified.	Gerardo Pena (b) (4)	21 Apr 2021 14:20:07
	(b) (4)	
Signature has been broken.	Gerardo Pena (b) (4)	21 Apr 2021 14:20:07
	(b) (4)	
User entered missing code ND - Not Done; reason for	Gerardo Pena (b) (4)	21 Apr 2021 14:20:07
change Data Entry Error	(b) (4)	
User closed query 'Per source, subject reported fever.	(b) (4), (b) (6)	16 Apr 2021 21:27:38
Please review and reconcile. ' (Site from CRA).		
DataPoint Verified.		16 Apr 2021 21:27:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
	(b) (4)	
Query 'Per source, subject reported fever. Please	(b) (4), (b) (6)	14 Apr 2021 01:13:47
review and reconcile. ' answered with 'Updated ' (Site		
from CRA).		
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 01:13:30
User entered '36.8' C reason for change: Data Entry	(b) (4), (b) (6)	14 Apr 2021 01:13:30
Error		
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:02
User opened query 'Per source, subject reported	(b) (4), (b) (6)	13 Apr 2021 20:51:11
fever. Please review and reconcile. ' (Site from CRA).		
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered missing code ND - Not Done; reason for	Nathan Cortez (b) (4)	31 Dec 2020 18:59:53
change Data Entry Error		
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38



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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User closed query 'Per progress note dated 17Nov2020, subject experienced mild body aches. please review and reconcile.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:27:35
	(b) (4), (b) (6)	16 Apr 2021 21:27:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Query 'Per progress note dated 17Nov2020, subject experienced mild body aches. please review and reconcile.' answered with 'Updated ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 01:13:59
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 01:13:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 01:13:30
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:02
User opened query 'Per progress note dated 17Nov2020, subject experienced mild body aches. please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:49:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Moderate (Moderate)'	(b) (4)	
	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38
	(b) (4), (b) (6)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:33:11**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (3)**

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38



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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

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Form: Symptom Log (3)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 20:52:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:55:47
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 15:35:38

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 4 (Day 4)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:10:54
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:57:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '18 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:10:55
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:57:22
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:10:52
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:57:21
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
User entered '98'	Nathan Cortez (b) (4)	20 Nov 2020 15:42:23



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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	20 Nov 2020 15:42:23

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	21 Apr 2021 16:37:42
User closed query 'Per Illness visit date 18NOV20 Vitals signs this value is 36.8' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:37:40
Query 'Per Illness visit date 18NOV20 Vitals signs this value is 36.8' answered with 'updated. note: there is a value under vital signs and another under covid-19 symptoms. this value is in the latter.' (Site from CRA).	Gerardo Pena (b) (4)	21 Apr 2021 14:21:49
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	21 Apr 2021 14:21:44
User entered '37.2' C reason for change: Data Entry Error	(b) (4)	
	Gerardo Pena (b) (4)	21 Apr 2021 14:21:44
User opened query 'Per Illness visit date 18NOV20 Vitals signs this value is 36.8' (Site from CRA).	(b) (4)	
Query 'Value not updated per COVID-19 Contact source. Please reconcile.' canceled (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:30:16
User opened query 'Value not updated per COVID-19 Contact source. Please reconcile.' (Site from CRA).		20 Apr 2021 16:25:52
User closed query 'Per source, Temperature is 37.2' (Site from CRA).		19 Apr 2021 16:10:10
DataPoint Un-verified.		19 Apr 2021 16:10:10
DataPoint Verified.		16 Apr 2021 21:28:34
DataPoint Un-verified.		16 Apr 2021 21:28:28
DataPoint Verified.		16 Apr 2021 21:27:51
User signature succeeded.		16 Apr 2021 21:27:48
Query 'Per source, Temperature is 37.2' answered with 'Updated ' (Site from CRA).	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 01:14:58
User entered '36.2' C reason for change: Data Entry Error		14 Apr 2021 01:14:40
User opened query 'Per source, Temperature is 37.2' (Site from CRA).		14 Apr 2021 01:14:40
		13 Apr 2021 20:56:15

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.8' C	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:10:22
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:57:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:10:24
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:57:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:10:57
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:57:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:10:59
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:57:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:10:25
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:57:52
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23



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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:11:00
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:57:54
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:10:29
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:57:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

US3292320

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:10:31
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:58:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:11:02
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:58:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

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Form: Symptom Log (4)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:11:07
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:58:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

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Form: Symptom Log (4)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:10:38
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:59:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:11:09
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:59:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:11:10
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:59:08
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	Nathan Cortez (b) (4) (b) (4)	20 Nov 2020 15:42:23



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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:11:12
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:59:10
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:11:13
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:59:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:10:35
DataPoint Un-verified.		16 Apr 2021 21:28:34
DataPoint Verified.		13 Apr 2021 20:59:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 15:42:23

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 5 (Day 5)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '19 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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Form: Symptom Log (5)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '97'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (5)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	20 Nov 2020 16:02:38



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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '37.5' C	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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Form: Symptom Log (5)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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Form: Symptom Log (5)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:33:11**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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Form: Symptom Log (5)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38



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**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:33:11**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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Form: Symptom Log (5)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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**Form: Symptom Log (5)**

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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Form: Symptom Log (5)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38



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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		13 Apr 2021 21:00:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	20 Nov 2020 16:02:38

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 6 (Day 6)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:47:44

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '20 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

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Form: Symptom Log (6)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '97'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	23 Nov 2020 21:47:44

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Form: Symptom Log (6)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.8' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

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Form: Symptom Log (6)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44



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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:47:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 7 (Day 7)'	(b) (4) Gerardo Pena (b) (4)	24 Nov 2020 17:05:42



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Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '21 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '96'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	24 Nov 2020 17:05:42

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.2' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42



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Form: Symptom Log (7)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	24 Nov 2020 17:05:42

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 8 (Day 8)'	(b) (4) Gerardo Pena (b) (4)	25 Nov 2020 17:24:32

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '22 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32



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Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '97'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '35.4' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 16:33:11**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 16:33:11**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:24:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 9 (Day 9)'	(b) (4) Gerardo Pena (b) (4)	25 Nov 2020 17:29:15

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '23 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '98'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	25 Nov 2020 17:29:15



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.0' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Severe (Severe)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Severe (Severe)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 16:33:11**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	25 Nov 2020 17:29:15

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 10 (Day 10)'	(b) (4) Kevin Martinez (b) (4)	30 Nov 2020 20:47:34

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '24 Nov 2020'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '97'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.6' C	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 16:33:11**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Kevin Martinez (b) (4)	30 Nov 2020 20:47:34



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 16:33:11**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 16:33:11**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:17
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Kevin Martinez (b) (4) (b) (4)	30 Nov 2020 20:47:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 11 (Day 11)'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 15:55:43



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '25 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '97'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '35.6' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43



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Form: Symptom Log (11)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

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Form: Symptom Log (11)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 15:55:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 12 (Day 12)'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 22:16:44

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:17:10
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '26 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:17:12
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:17:15
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '98'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	01 Dec 2020 22:16:44

US3292320

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User closed query 'Per source this is 36.1.' (Site from CRA).		21 Apr 2021 16:39:07
DataPoint Verified.		21 Apr 2021 16:39:03
Query 'Per source this is 36.1.' answered with 'original record 97.1 degrees Fahrenheit. Rounded up after conversion' (Site from CRA).	Gerardo Pena (b) (4)	21 Apr 2021 14:27:50
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User opened query 'Per source this is 36.1.' (Site from CRA).		16 Apr 2021 21:00:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.2' C	(b) (4)	01 Dec 2020 22:16:44
	Gerardo Pena (b) (4)	
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:17:27
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:17:29
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:19:10
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:19:12
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:19:15
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:19:17
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:19:24
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:19:27
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:17:24
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:17:26
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:33:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:19:29
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

US3292320

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:19:31
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:19:32
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44



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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:19:33
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:19:35
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:19:37
DataPoint Un-verified.		16 Apr 2021 21:28:38
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 22:16:44

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Folder: Covid-19 Assessment 17 Nov 2020

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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**Folder: Covid-19 Assessment 17 Nov 2020**

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**Generated On: 09 Jun 2021 16:33:11**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '99'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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Folder: Covid-19 Assessment 17 Nov 2020

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	02 Dec 2020 14:39:32



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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '35.5' C	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 09 Jun 2021 16:33:11**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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Form: Symptom Log (13)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	02 Dec 2020 14:39:32

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Form: Symptom Log (13)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	02 Dec 2020 14:39:32

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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Form: Symptom Log (13)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32



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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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Form: Symptom Log (13)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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**Folder: Covid-19 Assessment 17 Nov 2020**

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32



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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:39:32

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 09 Jun 2021 16:33:11**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '28 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4), (b) (6)	02 Dec 2020 14:42:01

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Form: Symptom Log (14)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '97'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	02 Dec 2020 14:42:01

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.2' C	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 09 Jun 2021 16:33:11**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01



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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 09 Jun 2021 16:33:11**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 09 Jun 2021 16:33:11**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 09 Jun 2021 16:33:11**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	02 Dec 2020 14:42:01

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:42:01

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34



**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 09 Jun 2021 16:33:11**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '29 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4), (b) (6)	02 Dec 2020 15:37:34

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '97'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.3' C	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34



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**Form: Symptom Log (15)**

**Generated On: 09 Jun 2021 16:33:11**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 09 Jun 2021 16:33:11**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:37:34

US3292320

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Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 16 (Day 16)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (16)**

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21



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Form: Symptom Log (16)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '98'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	02 Dec 2020 20:00:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 16:33:11**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	02 Dec 2020 20:00:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21



**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:00:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 17 (Day 17)'	(b) (4), (b) (6)	03 Dec 2020 14:20:36

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '1 Dec 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '98'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	03 Dec 2020 14:20:36



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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36



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Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 14:20:36

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

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**Form: Symptom Log (17)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 14:20:36

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36



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Folder: Covid-19 Assessment 17 Nov 2020

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Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:20:36

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 18 (Day 18)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 09 Jun 2021 16:33:11**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '2 Dec 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '97'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	03 Dec 2020 16:36:32

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Folder: Covid-19 Assessment 17 Nov 2020

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 16:36:32

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32



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Form: Symptom Log (18)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 16:36:32

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (18)**

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

US3292320

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Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 09 Jun 2021 16:33:11**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 09 Jun 2021 16:33:11**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:36:32

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 19 (Day 19)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21



**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 09 Jun 2021 16:33:11**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '3 Dec 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 09 Jun 2021 16:33:11**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 20:15:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '98'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	03 Dec 2020 20:15:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.0' C	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 09 Jun 2021 16:33:11**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 09 Jun 2021 16:33:11**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 20:15:21

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 09 Jun 2021 16:33:11**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 09 Jun 2021 16:33:11**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 20:15:21

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 09 Jun 2021 16:33:11**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:15:21

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 20 (Day 20)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:41

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '4 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:41

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 15:49:41



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '97'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:41

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	07 Dec 2020 15:49:41

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.2' C	(b) (4), (b) (6)	07 Dec 2020 15:49:41

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:41

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 09 Jun 2021 16:33:11**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 15:49:41

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:41

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:41

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:41



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 15:49:41

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 15:49:41

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:41

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 09 Jun 2021 16:33:11**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 15:49:41

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 15:49:41

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:41

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:41

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 09 Jun 2021 16:33:11**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 15:49:41



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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 15:49:41

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 15:49:41

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:41

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 21 (Day 21)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:08:50

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '5 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:08:50

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 09 Jun 2021 16:33:11**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 20:08:50

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '97'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:08:50

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	07 Dec 2020 20:08:50



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.4' C	(b) (4), (b) (6)	07 Dec 2020 20:08:50

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:08:50

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 09 Jun 2021 16:33:11**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:08:50

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:08:50

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:08:50

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 09 Jun 2021 16:33:11**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:08:50

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:08:50

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:08:50



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 20:08:50

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 09 Jun 2021 16:33:11**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:08:50

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 09 Jun 2021 16:33:11**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 20:08:50

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (21)**

**Generated On: 09 Jun 2021 16:33:11**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:08:50

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:08:50

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 20:08:50

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 20:08:50

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 20:08:50



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Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 20:08:50

US3292320

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Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 22 (Day 22)'	(b) (4) Gerardo Pena (b) (4)	07 Dec 2020 21:07:06

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:20:38
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '6 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:20:39
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.		
	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered '0'	Gerardo Pena (b) (4)	07 Dec 2020 21:07:06
	(b) (4)	

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Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User closed query 'Per source this is 98%.' (Site from CRA).	(b) (4)	21 Apr 2021 16:39:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:39:21
Query 'Per source this is 98%.' answered with 'updated' (Site from CRA).	Gerardo Pena (b) (4)	21 Apr 2021 14:31:08
Signature has been broken.	(b) (4)	21 Apr 2021 14:31:00
User entered '98' reason for change: Data Entry Error	Gerardo Pena (b) (4)	21 Apr 2021 14:31:00
DataPoint Un-verified.	(b) (4)	16 Apr 2021 21:28:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User opened query 'Per source this is 98%.' (Site from CRA).	(b) (4)	16 Apr 2021 21:11:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '96'	(b) (4)	07 Dec 2020 21:07:06
	Gerardo Pena (b) (4)	
	(b) (4)	

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (22)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	07 Dec 2020 21:07:06

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:20:42
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.2' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:21:01
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:21:03
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:21:05
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:21:07
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:21:09
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:21:11
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:21:12
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:21:14
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:21:15
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:21:17
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:20:58
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:20:53
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:21:19
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:21:21
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:21:23
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		19 Apr 2021 16:21:24
DataPoint Un-verified.		16 Apr 2021 21:28:41
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 21:07:06

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 23 (Day 23)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19



**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (23)**

**Generated On: 09 Jun 2021 16:33:11**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '7 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '97'	(b) (4), (b) (6)	07 Dec 2020 22:43:19

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (23)**

**Generated On: 09 Jun 2021 16:33:11**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	07 Dec 2020 22:43:19

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '35.9' C	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 22:43:19

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (23)**

**Generated On: 09 Jun 2021 16:33:11**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (23)**

**Generated On: 09 Jun 2021 16:33:11**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 22:43:19

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (23)**

**Generated On: 09 Jun 2021 16:33:11**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 22:43:19



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (23)**

**Generated On: 09 Jun 2021 16:33:11**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:43:19

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 22:43:19

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 24 (Day 24)'	(b) (4) Gerardo Pena (b) (4)	10 Dec 2020 19:47:29

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User closed query 'per CDM: day 25 date also 9 Dec 2020, please clarify day 24's date' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:24:18
Query 'per CDM: day 25 date also 9 Dec 2020, please clarify day 24's date' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4)	23 Mar 2021 19:18:05
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
User entered '8 Dec 2020' reason for change: Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
User opened query 'per CDM: day 25 date also 9 Dec 2020, please clarify day 24's date' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 23:45:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '9 Dec 2020'	(b) (4)	
	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered '1' reason for change: Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered '0'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	



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Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered '97'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

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Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered empty.	System	23 Mar 2021 19:16:51
User entered '%'	System	10 Dec 2020 19:47:29

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered '36.2' C	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

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Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	



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Form: Symptom Log (24)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

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Form: Symptom Log (24)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

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Form: Symptom Log (24)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	



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Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
User entered empty; reason for change Per Query Resolution	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:16:51
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	10 Dec 2020 19:47:29
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 25 (Day 25)'	(b) (4) Gerardo Pena (b) (4)	10 Dec 2020 19:50:02

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '9 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '98'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	10 Dec 2020 19:50:02



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.1' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Dec 2020 19:50:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 26 (Day 26)'	(b) (4) Gerardo Pena (b) (4)	11 Dec 2020 14:42:33

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '10 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '97'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.2' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33



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Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	11 Dec 2020 14:42:33

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 27 (Day 27)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '98'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (27)**

**Generated On: 09 Jun 2021 16:33:11**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (27)**

**Generated On: 09 Jun 2021 16:33:11**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (27)**

**Generated On: 09 Jun 2021 16:33:11**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 18:02:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 28 (Day 28)'	(b) (4) Gerardo Pena (b) (4)	16 Dec 2020 15:31:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '12 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '98'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	16 Dec 2020 15:31:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '36.4' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43



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Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:31:43

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:33:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 29 (Day 29)'	(b) (4) Gerardo Pena (b) (4)	16 Dec 2020 15:35:15

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Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
User closed query 'per CDM: day 30 date also listed as 14 Dec 2020, please clarify day 29's date' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:24:32
Query 'per CDM: day 30 date also listed as 14 Dec 2020, please clarify day 29's date' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4)	23 Mar 2021 19:24:48
Signature has been broken.	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
User entered '13 Dec 2020' reason for change: Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
User opened query 'per CDM: day 30 date also listed as 14 Dec 2020, please clarify day 29's date' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 23:45:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '14 Dec 2020'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15

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Form: Symptom Log (29)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered '1' reason for change: Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered '0'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered '98'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered empty.	System	23 Mar 2021 19:24:41
User entered '%'	System	16 Dec 2020 15:35:15



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Form: Symptom Log (29)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered '36.4' C	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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Form: Symptom Log (29)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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Form: Symptom Log (29)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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Form: Symptom Log (29)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	



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Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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Form: Symptom Log (29)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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Form: Symptom Log (29)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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Form: Symptom Log (29)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	



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Form: Symptom Log (29)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:59
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Gerardo Pena (b) (4)	23 Mar 2021 19:24:41
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
User entered 'None (None)'	Gerardo Pena (b) (4)	16 Dec 2020 15:35:15
	(b) (4)	

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Form: Symptom Log (30)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 30 (Day 30)'	(b) (4) Gerardo Pena (b) (4)	16 Dec 2020 15:41:10

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Form: Symptom Log (30)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '14 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

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Form: Symptom Log (30)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '98'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
Query 'per source this is 36.6.' canceled (Site from CRA).		16 Apr 2021 21:25:32
User opened query 'per source this is 36.6.' (Site from CRA).		16 Apr 2021 21:24:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '35.5' C	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Dec 2020 15:41:10

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Form: Symptom Log (31)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Day 31 (Day 31)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02



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Generated On: 09 Jun 2021 16:33:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (31)**

**Generated On: 09 Jun 2021 16:33:11**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '99'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:33:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
User entered '%'	System	17 Dec 2020 17:27:02

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:33:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '37.1' C	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:33:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (31)**

**Generated On: 09 Jun 2021 16:33:11**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:33:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:33:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:33:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:33:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:33:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:33:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:33:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (31)**

**Generated On: 09 Jun 2021 16:33:11**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02



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Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:33:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

**US3292320**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (31)**

**Generated On: 09 Jun 2021 16:33:11**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (31)**

**Generated On: 09 Jun 2021 16:33:11**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:33:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.	(b) (4)	16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:33:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:02
DataPoint Verified.		16 Apr 2021 21:28:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:27:02

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 16:33:11**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:24:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '18 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:23:14

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 16:33:11**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4)	19 Apr 2021 16:24:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:23:14

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:33:11

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4)	19 Apr 2021 16:24:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 10:39:18
Query 'Thank you for your previous response however the an AE of COVID-19 has not been captured as expected.' canceled (Site from CRA).	(b) (4)	03 Dec 2020 00:13:34
User opened query 'Thank you for your previous response however the an AE of COVID-19 has not been captured as expected.' (Site from CRA).	(b) (4)	03 Dec 2020 00:11:52
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Confirmed' (Site from System).	Nathan Cortez (b) (4)	23 Nov 2020 16:23:21
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	23 Nov 2020 16:23:14
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	23 Nov 2020 16:23:14



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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.		19 Apr 2021 16:24:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '18 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:23:14

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:33:11

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.		19 Apr 2021 16:24:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:23:14

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.		19 Apr 2021 16:24:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:23:14

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[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)	01 May 2021 17:25:12
DataPoint Verified.		19 Apr 2021 16:24:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:23:14

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.		19 Apr 2021 16:24:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:23:14

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.		19 Apr 2021 16:24:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:23:14

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COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
User entered 'I'	System	23 Nov 2020 16:23:14

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Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.	(b) (4)	19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Gerardo Pena (b) (4)	21 Feb 2021 18:48:52
	(b) (4)	
	Nathan Cortez (b) (4)	23 Nov 2020 16:57:52
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.	(b) (4)	19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Gerardo Pena (b) (4)	21 Feb 2021 18:48:52
	(b) (4)	
	Nathan Cortez (b) (4)	23 Nov 2020 16:57:52
	(b) (4)	

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52



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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.	(b) (4)	19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Gerardo Pena (b) (4)	21 Feb 2021 18:48:52
	(b) (4)	
	Nathan Cortez (b) (4)	23 Nov 2020 16:57:52
	(b) (4)	

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Gerardo Pena (b) (4)	21 Feb 2021 18:48:52
	(b) (4)	
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[Start Date](#)

Audit	User	Time (GMT)
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DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.	(b) (4)	19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia section of this form and update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 13:43:10
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia section of this form and update accordingly' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4) (b) (4)	21 Feb 2021 18:49:01
User entered 'No (N)' reason for change: Data Entry Error	Gerardo Pena (b) (4) (b) (4)	21 Feb 2021 18:48:52
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia section of this form and update accordingly' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 19:06:59
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:57:52



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.	(b) (4)	19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Gerardo Pena (b) (4)	21 Feb 2021 18:48:52
	(b) (4)	
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:57:52
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
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User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Gerardo Pena (b) (4)	21 Feb 2021 18:48:52
	(b) (4)	
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:33:11

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.	(b) (4)	19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Gerardo Pena (b) (4)	21 Feb 2021 18:48:52
	(b) (4)	
	Nathan Cortez (b) (4)	23 Nov 2020 16:57:52
	(b) (4)	



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:33:11

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:33:11

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.	(b) (4)	19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Gerardo Pena (b) (4)	21 Feb 2021 18:48:52
	(b) (4)	
	Nathan Cortez (b) (4)	23 Nov 2020 16:57:52
	(b) (4)	

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:33:11

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:33:11

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.	(b) (4)	19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Gerardo Pena (b) (4)	21 Feb 2021 18:48:52
	(b) (4)	
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:57:52
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:33:11

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:33:11

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.	(b) (4)	19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Gerardo Pena (b) (4)	21 Feb 2021 18:48:52
	(b) (4)	
	Nathan Cortez (b) (4)	23 Nov 2020 16:57:52
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:33:11

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Folder: Covid-19 Assessment 17 Nov 2020

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
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	23 Nov 2020 16:57:57
User entered 'No (N)' reason for change: Data Entry Error	System	23 Nov 2020 16:57:57
User opened query 'Data is required. Please complete.' (Site from System).	Nathan Cortez (b) (4)	23 Nov 2020 16:57:52
User entered empty.		



US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:33:11

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:33:11

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:18
DataPoint Verified.		19 Apr 2021 16:24:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 16:57:52

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:33:11

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:23
DataPoint Verified.	(b) (4)	19 Apr 2021 16:24:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Jan 2021 17:57:48

**US3292320**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
User accepted default value 'Day 3 (Day 3)'	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

**US3292320**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.		12 Apr 2021 16:27:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

**US3292320**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.		12 Apr 2021 16:27:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '20 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

**US3292320**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
User accepted default value 'Day 5 (Day 5)'	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

**US3292320**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	23 Nov 2020 17:03:23



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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:33:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.	(b) (4)	12 Apr 2021 16:27:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 06:46:20
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with '24Nov2020 sample was collected on Day 7.' (Site from DM).	Gerardo Pena (b) (4) (b) (4)	07 Dec 2020 22:39:21
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:15:25
User entered '22 Nov 2020'	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

**US3292320**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
User accepted default value 'Day 7 (Day 7)'	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:33:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.		12 Apr 2021 16:27:51
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 09:18:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Gerardo Pena (b) (4)	07 Dec 2020 22:37:36
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Pending' (Site from System).	Nathan Cortez (b) (4)	23 Nov 2020 17:03:33
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 17:03:23
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:33:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.		12 Apr 2021 16:27:51
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '24 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Gerardo Pena (b) (4)	07 Dec 2020 22:37:36
	(b) (4)	
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

**US3292320**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
User accepted default value 'Day 9 (Day 9)'	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:33:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.		12 Apr 2021 16:28:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 09:18:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Gerardo Pena (b) (4)	07 Dec 2020 22:37:56
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Pending' (Site from System).	Nathan Cortez (b) (4)	23 Nov 2020 17:03:37
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 17:03:23
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:28:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '26 Nov 2020' reason for change: Data Entry Error	Gerardo Pena (b) (4)	07 Dec 2020 22:37:56
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 16:33:11**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
User accepted default value 'Day 14 (Day 14)'	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23



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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:33:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.		12 Apr 2021 16:30:38
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 09:18:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Gerardo Pena (b) (4)	07 Dec 2020 22:38:14
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Pending' (Site from System).	Nathan Cortez (b) (4)	23 Nov 2020 17:03:41
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 17:03:23
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:33:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:38
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08DEC2020 is reported under Illness 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 appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 06:36:10
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08DEC2020 is reported under Illness 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 appropriate visit. Else clarify, thank you. ' answered with 'Updated' (Site from DM).	Nathan Cortez (b) (4)	31 Dec 2020 20:32:03
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08DEC2020 is reported under Illness 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 appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 06:36:33
User entered '1 Dec 2020' reason for change: Data Entry Error	Gerardo Pena (b) (4)	07 Dec 2020 22:38:14
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

**US3292320**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
User accepted default value 'Day 21 (Day 21)'	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:33:11

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.		12 Apr 2021 16:30:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Nathan Cortez (b) (4)	31 Dec 2020 20:31:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 09:18:15
Query 'Data is required. Please complete.' answered with 'Pending' (Site from System).	Nathan Cortez (b) (4)	23 Nov 2020 17:03:46
User opened query 'Data is required. Please complete.' (Site from System).		
	System	23 Nov 2020 17:03:23
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:56
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
User entered '08 Dec 2020' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 20:31:15
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
User accepted default value 'Day 28 (Day 28)'	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:33:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:28:52
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Per CDM: Response noted "Pending". Please complete once data available' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 07:42:30
Query 'Per CDM: Response noted "Pending". Please complete once data available' answered with 'Updated' (Site from DM).	Nathan Cortez (b) (4)	31 Dec 2020 20:31:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 20:31:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Dec 2020 15:19:31
User opened query 'Per CDM: Response noted "Pending". Please complete once data available' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 09:19:31
Query 'Data is required. Please complete.' answered with 'Pending' (Site from System).	Nathan Cortez (b) (4)	23 Nov 2020 17:03:49
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 17:03:23
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:28:53
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
User entered '15 Dec 2020' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 20:31:48
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 17:03:23



**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:22
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:34:08
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	20 Nov 2020 16:08:05

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:22
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 15 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 13:49:02
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 15 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Updated' (Site from DM).	Nathan Cortez (b) (4)	31 Dec 2020 20:51:31
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 15 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 07:34:51
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:34:09
User entered '18 Nov 2020'	Nathan Cortez (b) (4)	20 Nov 2020 16:08:05

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:22
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:34:10
User entered 'Home (Home)'	Nathan Cortez (b) (4)	20 Nov 2020 16:08:05

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:22
User entered 'SICKD1'	System	20 Nov 2020 16:08:05

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:35:12
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	20 Nov 2020 16:09:03

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:35:13
User entered '18 Nov 2020'	Nathan Cortez (b) (4)	20 Nov 2020 16:09:03

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:35:14
User entered '15:27'	Nathan Cortez (b) (4)	20 Nov 2020 16:09:03

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User entered '18 Nov 2020 15:27'	System	20 Nov 2020 16:09:03



US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:35:16
User entered '175.3' cm	Nathan Cortez (b) (4)	20 Nov 2020 16:09:03
DataPoint set to visible.	System	20 Nov 2020 16:08:05

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:35:17
User entered '92.5' kg	Nathan Cortez (b) (4)	20 Nov 2020 16:09:03
DataPoint set to visible.	System	20 Nov 2020 16:08:05

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:35:19
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Nov 2020 16:09:10
User entered '36.8' C reason for change: Data Entry Error	Nathan Cortez (b) (4)	20 Nov 2020 16:09:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Nov 2020 16:09:03
User entered '36.8' (non-conformant).	Nathan Cortez (b) (4)	20 Nov 2020 16:09:03

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:35:20
User entered 'Oral (Oral)'	Nathan Cortez (b) (4)	20 Nov 2020 16:09:03

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:35:21
User entered empty.	Nathan Cortez (b) (4)	20 Nov 2020 16:09:03

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:35:23
User entered '79'	Nathan Cortez (b) (4)	20 Nov 2020 16:09:03

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User entered 'bpm'	System	20 Nov 2020 16:09:03

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:35:24
User entered '17'	Nathan Cortez (b) (4)	20 Nov 2020 16:09:03



US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User entered 'breaths/min'	System	20 Nov 2020 16:09:03

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:35:25
User entered '139'	Nathan Cortez (b) (4)	20 Nov 2020 16:09:03

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User entered 'mmHg'	System	20 Nov 2020 16:09:03

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:35:27
User entered '79'	Nathan Cortez (b) (4)	20 Nov 2020 16:09:03

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26
User entered 'mmHg'	System	20 Nov 2020 16:09:03

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:26

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:33:11**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:35:55
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	20 Nov 2020 16:09:18



**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:33:11**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:35:57
User entered '18 Nov 2020'	Nathan Cortez (b) (4)	20 Nov 2020 16:09:18

US3292320

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:33:11

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:33
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:36:21
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	20 Nov 2020 16:09:32

**US3292320**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 16:33:11**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:33
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:36:22
User entered '18 Nov 2020'	Nathan Cortez (b) (4)	20 Nov 2020 16:09:32

**US3292320**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:42
DataPoint Verified.		19 Apr 2021 16:30:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:47:41

**US3292320**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:42
DataPoint Verified.		19 Apr 2021 16:30:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '15 Dec 2020'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:47:41

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:42
DataPoint Verified.		19 Apr 2021 16:30:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Home (Home)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:47:41

**US3292320**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:42
User entered 'SICKD28'	System	31 Dec 2020 20:47:41

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
DataPoint Verified.		19 Apr 2021 16:30:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:44



**US3292320**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
DataPoint Verified.		19 Apr 2021 16:30:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '15 Dec 2020'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:44

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
DataPoint Verified.		19 Apr 2021 16:30:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '14:56'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:44

**US3292320**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
User entered '15 Dec 2020 14:56'	System	31 Dec 2020 20:48:44

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
DataPoint Verified.		19 Apr 2021 16:30:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '175.3' cm	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:44
DataPoint set to visible.	System	31 Dec 2020 20:47:41

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
DataPoint Verified.		19 Apr 2021 16:30:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '92.5' kg	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:44
DataPoint set to visible.	System	31 Dec 2020 20:47:41

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
DataPoint Verified.		19 Apr 2021 16:30:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '37.1' C	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:44

**US3292320**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:30:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Oral (Oral)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:44

**US3292320**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:30:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:44



**US3292320**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
DataPoint Verified.		19 Apr 2021 16:30:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '78'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:44

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
User entered 'bpm'	System	31 Dec 2020 20:48:44

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
DataPoint Verified.		19 Apr 2021 16:30:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '16'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:44

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
User entered 'breaths/min'	System	31 Dec 2020 20:48:44

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
DataPoint Verified.		19 Apr 2021 16:30:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '140'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:44

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
User entered 'mmHg'	System	31 Dec 2020 20:48:44

**US3292320**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
DataPoint Verified.		19 Apr 2021 16:30:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '73'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:44

**US3292320**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:33:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46
User entered 'mmHg'	System	31 Dec 2020 20:48:44



US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:33:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:46

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:33:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:49
DataPoint Verified.		19 Apr 2021 16:30:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:54

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:33:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:49
DataPoint Verified.		19 Apr 2021 16:30:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '15 Dec 2020'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:48:54

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:33:11

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:52
DataPoint Verified.		19 Apr 2021 16:30:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:49:03

**US3292320**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 16:33:11**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:52
DataPoint Verified.		19 Apr 2021 16:30:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '15 Dec 2020'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 20:49:03

US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.		19 Apr 2021 16:34:53
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:13:49

US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.		19 Apr 2021 16:34:53
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered '2 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:13:49



US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:33:11

[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 10:44:05
DataPoint Verified.		19 Apr 2021 16:34:53
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:13:49

**US3292320**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:33:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
User entered 'UNBLND_DECIDE'	System	03 Mar 2021 19:13:49

US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:33:11

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.		20 Apr 2021 20:38:03
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered '2 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:14:13

**US3292320**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:33:11**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	20 Apr 2021 20:38:03
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:23:29
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:47:09

US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:33:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.		20 Apr 2021 20:38:03
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:14:13

**US3292320**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:33:11**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:38:03
User entered 'Amendment 6 or later (Amendment 6 or later)'		20 Apr 2021 19:23:29
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:47:09

US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:33:11

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.		20 Apr 2021 20:38:03
User closed query 'Please provide unblinding documentation to subject's chart. ' (Site from CRA).		20 Apr 2021 20:38:01
Query 'Please provide unblinding documentation to subject's chart. ' answered with 'updated' (Site from CRA).		20 Apr 2021 19:24:01
User opened query 'Please provide unblinding documentation to subject's chart. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:38:37
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
	(b) (4)	
User entered '2 Mar 2021'	Gerardo Pena (b) (4)	03 Mar 2021 19:14:13
	(b) (4)	

US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:33:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:38:03
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered 'Placebo (Placebo)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:14:13



US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:33:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.		20 Apr 2021 20:38:03
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered 'Placebo (Placebo)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:14:13

US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:33:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.		20 Apr 2021 20:38:03
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered 'Placebo (Placebo)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:14:13

US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:33:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.		20 Apr 2021 20:38:03
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:14:13

**US3292320**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:33:11**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
User entered 'I'	System	03 Mar 2021 19:14:13

**US3292320**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:33:11**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
User entered empty.	System	03 Mar 2021 19:14:13

US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:33:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.	(b) (4)	19 Apr 2021 16:43:01
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:14:32

US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:33:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:43:01
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered '2 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:14:32

US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:33:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.		19 Apr 2021 16:43:01
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered '11:38'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:14:32



**US3292320**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:33:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
User entered '2 Mar 2021 11:38'	System	03 Mar 2021 19:14:32

**US3292320**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:33:11**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:43:06
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:14:46

US3292320

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:33:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.		19 Apr 2021 16:43:06
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).		08 Apr 2021 10:16:10
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' answered with 'Subject ID: US3292320 Accession Number: 1F60BVE Drawdate 02MAR21 Results report generated 06MAR2021	Antonio Gutierrez (b) (4)	01 Apr 2021 18:27:57
These queries NEED TO BE VERIFEIED BEFORE THEY ARE GENERATED. NEEDLESS QUERYING!' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:35:41
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered '2 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:14:46

**US3292320**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:33:11**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
DataPoint Verified.		19 Apr 2021 16:43:06
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:47
User entered '11:45'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 19:14:46

**US3292320**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:33:11**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:05
User entered '2 Mar 2021 11:45'	System	03 Mar 2021 19:14:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 16:33:11**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 16:10:39

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:57
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:01
User entered	System	23 Sep 2020 14:38:57
'USA-US072-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	23 Sep 2020 14:38:57

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Cartilage injury, LLT: Acetabular labral tear - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 21:52:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 21:52:36
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:06:01
User closed query 'Per discharge summary from hospital, subject was also diagnosed with the following: Leukocytosis, Urinary Retention, Foraminal hip stenosis L4/L5, Bilateral Hip Osteoarthritis, Trochanteric Bursitis, Iliotibial Band Syndrome. Please update Adverse Event Log as necessary. ' (Site from CRA).		06 Nov 2020 19:05:57
Query 'Per discharge summary from hospital, subject was also diagnosed with the following: Leukocytosis, Urinary Retention, Foraminal hip stenosis L4/L5, Bilateral Hip Osteoarthritis, Trochanteric Bursitis, Iliotibial Band Syndrome. Please update Adverse Event Log as necessary. ' answered with 'Updated' (Site from CRA).	Antonio Gutierrez (b) (4)	05 Nov 2020 18:24:38
Data point term sent to Coder	System	04 Nov 2020 23:56:25
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	04 Nov 2020 23:55:37
Coding entries removed.	Antonio Gutierrez (b) (4)	04 Nov 2020 23:55:37
User entered 'Left HIP LABRUM TEAR' reason for change: New Information	Antonio Gutierrez (b) (4)	04 Nov 2020 23:55:37
User opened query 'Per discharge summary from hospital, subject was also diagnosed with the following: Leukocytosis, Urinary Retention, Foraminal hip stenosis L4/L5, Bilateral Hip Osteoarthritis, Trochanteric Bursitis, Iliotibial Band Syndrome. Please update Adverse Event Log as necessary. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 18:49:34



US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per discharge summary from hospital, subject was also diagnosed with the following: Leukocytosis Urinary Retention Foraminal hip stenosis L4/L5 Bilateral Hip Osteoarthritis Trochanteric Bursitis Iliotibial Band Syndrome  Please update Adverse Event Log as necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 18:48:52
User opened query 'Per discharge summary from hospital, subject was also diagnosed with the following: Leukocytosis Urinary Retention Foraminal hip stenosis L4/L5 Bilateral Hip Osteoarthritis Trochanteric Bursitis Iliotibial Band Syndrome		23 Oct 2020 18:40:39
Please update Adverse Event Log as necessary.' (Site from CRA).		
DataPoint Verified.		02 Oct 2020 20:58:57
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Cartilage injury, LLT: Cartilage injury - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 14:09:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 14:09:59
Data point term sent to Coder	System	22 Sep 2020 22:59:27
Coding entries removed.	Antonio Gutierrez (b) (4)	22 Sep 2020 22:58:59
User entered 'RIGHT HIP LABRUM TEAR' reason for change: New Information	Antonio Gutierrez (b) (4)	22 Sep 2020 22:58:59
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Hip injury - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 07:49:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 07:49:42
Data point term sent to Coder	System	16 Sep 2020 16:13:32

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Right hip tear'	(b) (4), (b) (6)	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:57
User entered 'Yes (Y)'		16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:57
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 16:13:05

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:57
User entered 'No (N)'		16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:57
User entered '27 Aug 2020'	(b) (4), (b) (6)	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:57
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 16:13:05



US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 18:37:21
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	31 Dec 2020 18:43:52
DataPoint Un-verified.	Nathan Cortez (b) (4)	31 Dec 2020 18:43:52
User entered 'No (N)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 18:43:52
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	31 Dec 2020 18:43:21
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:57
User entered 'Yes (Y)'		16 Sep 2020 16:13:05

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 18:37:19
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		04 Jan 2021 14:52:23
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Per PI, new baseline achieved' (Site from Safety).	Nathan Cortez (b) (4)	31 Dec 2020 18:43:39
DataPoint Un-verified.	Nathan Cortez (b) (4)	31 Dec 2020 18:43:21
User entered '31 Dec 2020' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 18:43:21
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:55:38
DataPoint Verified.		06 Nov 2020 19:06:37
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		06 Nov 2020 13:14:12
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'This is unknown. Patient was to follow up with pain specialists and neurosurgery, but has opted out of any surgical or procedural interventions. No updates noted.' (Site from Safety).	Antonio Gutierrez (b) (4)	05 Nov 2020 18:26:09
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 20:12:27

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:15:45
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'pending' (Site from Safety).	Victoria Hernandez (b) (4)	13 Oct 2020 21:07:23
DataPoint Un-verified.	(b) (4), (b) (6)	02 Oct 2020 20:59:03
DataPoint Verified.		02 Oct 2020 20:58:57
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		02 Oct 2020 16:28:22
User entered empty.		16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:57
User entered empty.		16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:57
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	Antonio Gutierrez (b) (4)	22 Sep 2020 22:58:59
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 20:58:57
User entered 'Yes (Y)' reason for change: New Information	Antonio Gutierrez (b) (4)	22 Sep 2020 22:58:59
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:57
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 16:13:05



US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:57
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:57
User entered '1' reason for change: New Information	Antonio Gutierrez (b) (4)	22 Sep 2020 22:58:59
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:57
User entered '30 Aug 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	22 Sep 2020 22:58:59
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:13:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	04 Nov 2020 23:07:24
User entered '4 Sep 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	04 Nov 2020 23:07:24
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:57
User entered '5 Sep 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	22 Sep 2020 22:58:59
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:57
User entered 'No (N)' reason for change: New Information	Antonio Gutierrez (b) (4)	22 Sep 2020 22:58:59
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:13:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:57
User entered empty.		16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:57
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:57
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 16:13:05



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:57
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 16:13:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:57
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:57
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Sep 2020 16:13:05

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:57
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 16:13:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 16:13:31
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:13:31
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 16:13:05
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:13:05

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:57
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	16 Sep 2020 16:13:31
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:13:31
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	16 Sep 2020 16:13:05
User entered '1'	(b) (4), (b) (6)	16 Sep 2020 16:13:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Please review and update.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:38:36
Query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Please review and update.' answered with 'pending' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	13 Oct 2020 21:11:29
User opened query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Please review and update.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 17:01:29
DataPoint Verified.		02 Oct 2020 20:58:57
User entered 'I'		16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:57
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 16:13:05

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 18:37:26
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		04 Jan 2021 14:52:16
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Per PI, new baseline achieved' (Site from Safety).	Nathan Cortez (b) (4)	31 Dec 2020 18:43:42
DataPoint Un-verified.	Nathan Cortez (b) (4)	31 Dec 2020 18:43:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Nathan Cortez (b) (4)	31 Dec 2020 18:43:21
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:55:53
DataPoint Verified.		06 Nov 2020 19:07:35
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		06 Nov 2020 13:14:17
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'This is unknown. Patient was to follow up with pain specialists and neurosurgery, but has opted out of any surgical or procedural interventions. No updates noted.' (Site from Safety).	Antonio Gutierrez (b) (4)	05 Nov 2020 18:26:46
User entered 'Unknown (UNKNOWN)' reason for change: New Information	Antonio Gutierrez (b) (4)	05 Nov 2020 18:26:35



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 20:12:46
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		14 Oct 2020 15:15:50
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'pending' (Site from Safety).	Victoria Hernandez (b) (4)	13 Oct 2020 21:11:20
DataPoint Un-verified.	(b) (4), (b) (6)	02 Oct 2020 20:59:11
DataPoint Verified.		02 Oct 2020 20:58:57
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		02 Oct 2020 16:28:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'		16 Sep 2020 16:13:05

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	06 Nov 2020 19:07:35
DataPoint Un-verified.	(b) (4), (b) (6)	02 Oct 2020 20:59:15
DataPoint Verified.		02 Oct 2020 20:58:57
User entered empty.		16 Sep 2020 16:13:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:07:35
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.' (Site from Safety).		06 Nov 2020 13:14:21
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.' answered with 'Emergency Dept/Clinic Course: Dilaudid 0.5mL x2 IV, Dexamethasone 10mg IV once, Fentanyl 100mcg/2mL IV once. No surgical interventions. Discharged with Cyclobenzaprine HCL tab 10mg tid, Methylprednisolone tab 4mg dosepak for 6 days.' (Site from Safety).	Antonio Gutierrez (b) (4)	05 Nov 2020 21:13:44
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)	05 Nov 2020 14:02:19
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.' (Site from Safety).		05 Nov 2020 14:02:17
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		05 Nov 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:02:14
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 'Summary emailed to provided email address 04NOV2020 @ 17:17 Central Time.' (Site from Safety).	Antonio Gutierrez (b) (4)	04 Nov 2020 23:17:31
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'MRI Pelvis/Hip: Mild bilateral hip osteoarthritis, small tearing of the superior lateral aspect of the L hip acetabular labrum, fluid inflammation. Secondary to recent trauma, trochanteric bursitis, or proximal IT band syndrome. MRI Lumbar Spine: Moderate/Severe right foraminal stenosis at L4/L5 with no significant spinal canal stenosis, also showed disc bulge in L1-S1.' (Site from Safety).	Antonio Gutierrez (b) (4)	04 Nov 2020 22:54:57
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'Baseline lumbar pain, obesity, history of frequent chiropractic manipulations of the R hip' (Site from Safety).	Antonio Gutierrez (b) (4)	04 Nov 2020 22:25:11
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.' answered with 'COVID-19 (In-house) SWAB NASOPHARYNGEAL NASOPHARYNGEAL CAVITY collected August 30, 2020 @ 13:05, Result: NEGATIVE' (Site from Safety).	Antonio Gutierrez (b) (4)	04 Nov 2020 21:31:50
DataPoint Un-verified.	(b) (4), (b) (6)	02 Oct 2020 20:59:17
DataPoint Verified.		02 Oct 2020 20:58:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:33:11

[Narrative](#)

Audit	User	Time (GMT)
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 Oct 2020 18:19:50
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.' (Site from Safety).		02 Oct 2020 16:29:27
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.' (Site from Safety).		02 Oct 2020 16:29:16
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		02 Oct 2020 16:29:06
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		02 Oct 2020 16:28:55
User entered 'Patient reported to clinic on 22SEP2020 for V2. During his visit, he reported to Sub-I and CRC that he was actually admitted to the hospital due to what was later diagnosed as a Right Hip Labrum Tear. Will update this post as more information is collected.' reason for change: New Information	Antonio Gutierrez (b) (4)	22 Sep 2020 22:58:59
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 22:58:59
User entered '0'	System	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	16 Sep 2020 16:13:05

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 22:58:59



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:33:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
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)	05 Nov 2020 17:48:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 17:48:23
Data point term sent to Coder	System	05 Nov 2020 17:48:10
User entered 'Leukocytosis'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

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**Folder: Adverse Events**

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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)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:33:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '30 Aug 2020'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User entered empty.	System	05 Nov 2020 17:47:10



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '4 Sep 2020'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User entered empty.	System	05 Nov 2020 17:47:10

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:33:11

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:33:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 14:16:08
Query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' answered with 'Removed' (Site from DM).	Nathan Cortez (b) (4)	31 Dec 2020 19:01:55
User opened query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 18:06:56
DataPoint Verified.		06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:33:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:33:11

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10



US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:33:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:33:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'None (NONE)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'l'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:33:11

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:37:36
DataPoint Un-verified.	Nathan Cortez (b) (4)	31 Dec 2020 19:01:49
User entered empty; reason for change Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 19:01:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Discovered while patient was hospitalized due to torn labrum. Patient continued to be afebrile. Primary differential believed to be leukocytosis secondary to steroid use.'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

**Serious Adverse Event Derived (CSA Programming Field Only)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User entered '0'	System	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49
User entered 'I'	System	05 Nov 2020 17:47:10

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:49

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:33:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User coded data point as SOC: Renal and urinary disorders, HLG: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 17:52:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 17:52:22
Data point term sent to Coder	System	05 Nov 2020 17:51:14
User entered 'Urinary Retention'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:33:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '30 Aug 2020'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User entered empty.	System	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '4 Sep 2020'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User entered empty.	System	05 Nov 2020 17:51:13



US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:33:11

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:33:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 07:58:49
Query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' answered with 'Updated' (Site from DM).	Nathan Cortez (b) (4)	31 Dec 2020 19:02:37
User opened query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 18:07:24
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:33:11

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'None (NONE)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:33:11

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:33:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per Narrative, a Catheter was placed. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 08:01:20
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per Narrative, a Catheter was placed. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'Updated' (Site from DM).	Nathan Cortez (b) (4)	31 Dec 2020 19:06:16
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per Narrative, a Catheter was placed. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 23:45:27
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'I'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:33:11

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:38:46
DataPoint Un-verified.	Nathan Cortez (b) (4)	31 Dec 2020 19:02:22
User entered empty; reason for change Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 19:02:22
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Discovered while patient was hospitalized for torn labrum. Catheter was placed, no further intervention required.'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

**Serious Adverse Event Derived (CSA Programming Field Only)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User entered '0'	System	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44
User entered 'I'	System	05 Nov 2020 17:51:13

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:55:44



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Vertebral foraminal stenosis, LLT: Lumbar foraminal stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 23:13:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 23:13:33
Data point term sent to Coder	System	05 Nov 2020 17:56:20
User entered 'Foraminal Stenosis L4/L5'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '30 Aug 2020'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User entered empty.	System	05 Nov 2020 17:55:46



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
DataPoint Verified.	(b) (4)	09 Apr 2021 18:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Un-verified.	(b) (4)	
	Gerardo Pena (b) (4)	17 Feb 2021 18:19:12
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Gerardo Pena (b) (4)	17 Feb 2021 18:19:12
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
DataPoint Verified.		09 Apr 2021 18:22:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Un-verified.	(b) (4)	
	Gerardo Pena (b) (4)	17 Feb 2021 18:19:12
	(b) (4)	
User entered '10 Sep 2020' reason for change: New Information	Gerardo Pena (b) (4)	17 Feb 2021 18:19:12
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User entered empty.	System	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 07:59:23
Query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' answered with 'Updated' (Site from DM).	Nathan Cortez (b) (4)	31 Dec 2020 19:06:42
User opened query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 18:07:43
DataPoint Verified.		06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46



US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'None (NONE)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'l'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

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Folder: Adverse Events

Form: Adverse Events (4)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
DataPoint Verified.	(b) (4)	09 Apr 2021 18:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Un-verified.	(b) (4)	
	Gerardo Pena (b) (4)	17 Feb 2021 18:19:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Gerardo Pena (b) (4)	17 Feb 2021 18:19:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Unknown (UNKNOWN)'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

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 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:33:11

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 18:39:00
DataPoint Un-verified.	Nathan Cortez (b) (4)	31 Dec 2020 19:06:37
User entered empty; reason for change Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 19:06:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Discovered while patient was hospitalized for torn labrum. Patient was due to follow up with neurosurgery, but at last visit, patient states he was not moving forward with any surgical intervention.'	Antonio Gutierrez (b) (4)	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User entered '0'	System	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23
User entered 'I'	System	05 Nov 2020 17:55:46

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:23

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:33:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Trochanteric bursitis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:22:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:22:25
Data point term sent to Coder	System	05 Nov 2020 18:22:01
User entered 'Trochanteric bursitis'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38



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Folder: Adverse Events

Form: Adverse Events (6)

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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 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:33:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '30 Aug 2020'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User entered empty.	System	05 Nov 2020 18:21:38

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:33:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
DataPoint Verified.	(b) (4)	09 Apr 2021 18:22:51
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
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)	05 Jan 2021 08:01:56
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 'Condition has reached new baseline, considered resolved.' (Site from DM).	Nathan Cortez (b) (4)	31 Dec 2020 19:14:34
DataPoint Un-verified.	Nathan Cortez (b) (4)	31 Dec 2020 19:14:08
User entered 'No (N)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 19:14:08
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 08:04:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:33:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
DataPoint Verified.	(b) (4)	09 Apr 2021 18:22:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	31 Dec 2020 19:15:03
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	31 Dec 2020 19:15:03
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	31 Dec 2020 19:14:50
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	31 Dec 2020 19:14:50
DataPoint Un-verified.	Nathan Cortez (b) (4)	31 Dec 2020 19:14:50
User entered '31 Dec 2020' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 19:14:50
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	31 Dec 2020 19:14:08
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User entered empty.	System	05 Nov 2020 18:21:38



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:33:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 07:59:54
Query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' answered with 'Updated' (Site from DM).	Nathan Cortez (b) (4)	31 Dec 2020 19:14:46
User opened query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 18:08:25
DataPoint Verified.		06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:33:11

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:33:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:33:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

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Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'None (NONE)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'l'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38



US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:33:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:33:11

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
DataPoint Verified.	(b) (4)	09 Apr 2021 18:22:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Un-verified.	(b) (4)	
	Nathan Cortez (b) (4)	31 Dec 2020 19:15:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Nathan Cortez (b) (4)	31 Dec 2020 19:15:03
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Unknown (UNKNOWN)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[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 13:13:09
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:33:11

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:23:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Un-verified.	(b) (4)	
	Nathan Cortez (b) (4)	31 Dec 2020 19:14:08
User entered empty; reason for change Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 19:14:08
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Discovered while patient was hospitalized for torn labrum. No further intervention noted. Patient was to follow up with pain specialists and neurosurgery, but patient opted out of any surgical interventions.'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User entered '0'	System	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09
User entered 'I'	System	05 Nov 2020 18:21:38

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:09



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:33:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Iliotibial band syndrome, LLT: Iliotibial band syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:25:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:25:21
Data point term sent to Coder	System	05 Nov 2020 18:24:07
User entered 'Iliotibial Band Syndrome'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:33:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:33:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '30 Aug 2020'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User entered empty.	System	05 Nov 2020 18:23:33



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:33:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
DataPoint Verified.		09 Apr 2021 18:25:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Un-verified.	(b) (4)	
	Gerardo Pena (b) (4)	17 Feb 2021 18:20:11
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Gerardo Pena (b) (4)	17 Feb 2021 18:20:11
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:33:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
DataPoint Verified.	(b) (4)	09 Apr 2021 18:25:22
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Un-verified.	(b) (4)	
	Gerardo Pena (b) (4)	17 Feb 2021 18:20:11
	(b) (4)	
User entered '10 Sep 2020' reason for change: New Information	Gerardo Pena (b) (4)	17 Feb 2021 18:20:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33
	(b) (4)	

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User entered empty.	System	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:33:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 08:00:15
Query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' answered with 'Updated' (Site from DM).	Nathan Cortez (b) (4)	31 Dec 2020 19:19:10
User opened query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 18:08:51
DataPoint Verified.		06 Nov 2020 19:07:35
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:33:11

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:33:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:33:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:33:11

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:33:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'None (NONE)'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'l'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:33:11

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
DataPoint Verified.	(b) (4)	09 Apr 2021 18:25:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Un-verified.	(b) (4)	
	Gerardo Pena (b) (4)	17 Feb 2021 18:20:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Gerardo Pena (b) (4)	17 Feb 2021 18:20:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:24:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 18:24:13
User entered 'Unknown (UNKNOWN)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	05 Nov 2020 18:24:13
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:23:33
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[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 13:13:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33



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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:33:11

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:25:30
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:13:48
DataPoint Un-verified.	Nathan Cortez (b) (4)	31 Dec 2020 19:19:06
User entered empty; reason for change New Information	Nathan Cortez (b) (4)	31 Dec 2020 19:19:06
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:35
User entered 'DISCOVERED WHILE PATIENT WAS HOSPITALIZED FOR TORN LABRUM. NO FURTHER INTERVENTION NOTED. PATIENT WAS TO FOLLOW UP WITH PAIN SPECIALISTS AND NEUROSURGERY, BUT PATIENT OPTED OUT OF ANY SURGICAL INTERVENTIONS.'	Antonio Gutierrez (b) (4)	05 Nov 2020 18:24:13
reason for change: New Information		
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User entered '0'	System	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18
User entered 'I'	System	05 Nov 2020 18:23:33

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:18

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:29:20
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:43
User entered 'USA-US072-2020-mRNA-1273-P301000014'	System	24 Nov 2020 13:54:38
User entered 'New'	(b) (4), (b) (6)	24 Nov 2020 13:54:38

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:33:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Nov 2020 12:07:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 12:07:01
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:29:27
Data point term sent to Coder	System	23 Nov 2020 16:28:21
User entered 'Positive Symptomatic COVID-19'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:29:31
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:29:33
User entered 'No (N)'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51



US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:33:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:29:36
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:29:39
User entered '15 Nov 2020'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:29:41
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 16:27:51

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:33:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:29:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Un-verified.	(b) (4)	
	Nathan Cortez (b) (4)	31 Dec 2020 19:58:33
User entered 'No (N)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 19:58:33
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:29:42
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:29:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Un-verified.	(b) (4)	
	Nathan Cortez (b) (4)	31 Dec 2020 19:58:33
User entered '7 Dec 2020' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 19:58:33
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:29:44
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:33:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:23:20
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Updated' (Site from Safety).	Nathan Cortez (b) (4)	31 Dec 2020 20:00:31
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 22:06:08
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:29:45
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 16:27:51



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:29:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:29:49
User entered 'No (N)'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:30:29
User entered '0'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:30:30
User entered '0'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:30:32
User entered '0'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:30:33
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:30:35
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:30:53
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51



**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:30:54
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:33:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:30:56
User entered '0'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:33:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:30:57
User entered '0'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:31:02
User entered '0'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:33:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:29:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:23:25
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Updated' (Site from Safety).	Nathan Cortez (b) (4)	31 Dec 2020 20:00:37
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 19:58:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Dec 2020 19:58:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 19:58:33
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 23:25:01
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 16:27:51
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:33:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:29:32
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Dec 2020 19:58:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Dec 2020 19:58:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 19:58:33
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 16:27:51
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:33:11

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:29:33
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'PV Query: As the last dose of study drug was given on 22Sep2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:23:33
User closed query 'PV Query: Please provide action taken with study drug for the event' (Site from Safety).		05 Jan 2021 16:23:28
Query 'PV Query: As the last dose of study drug was given on 22Sep2020, please update the action taken with study drug from none to not applicable.' answered with 'Updated' (Site from Safety).	Nathan Cortez (b) (4)	31 Dec 2020 20:00:43
Query 'PV Query: Please provide action taken with study drug for the event' answered with 'Updated' (Site from Safety).	Nathan Cortez (b) (4)	31 Dec 2020 20:00:40
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 19:58:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Dec 2020 19:58:33
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 19:58:33
User opened query 'PV Query: As the last dose of study drug was given on 22Sep2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 18:05:16
User opened query 'PV Query: Please provide action taken with study drug for the event' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 22:05:14
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 16:27:51
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:33:11

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:31:10
User entered 'I'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51



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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:33:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
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.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:23:39
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.' answered with 'None' (Site from Safety).	Nathan Cortez (b) (4)	31 Dec 2020 20:00:51
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.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 22:08:16
DataPoint Verified.		23 Nov 2020 17:31:12
User entered '0'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:31:13
User entered '0'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:33:11

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:29:35
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:23:44
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated' (Site from Safety).	Nathan Cortez (b) (4)	31 Dec 2020 20:00:55
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 19:58:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Dec 2020 19:58:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 19:58:33
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 22:07:13
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 16:27:51
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:31:17
User entered empty.	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:33:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'PV Query: Symptom logs for dates 08 Dec 2020 and 13 Dec2020 are missing. However, Symptom log for dates 09 Dec 2020 and 14 Dec2020 are repeated twice. Please update the CRF to reflect correct dates for missing Symptom log' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:23:48
Query 'PV Query: Symptom logs for dates 08 Dec 2020 and 13 Dec2020 are missing. However, Symptom log for dates 09 Dec 2020 and 14 Dec2020 are repeated twice. Please update the CRF to reflect correct dates for missing Symptom log' answered with 'Updated' (Site from Safety).	Nathan Cortez (b) (4)	31 Dec 2020 20:02:21
User opened query 'PV Query: Symptom logs for dates 08 Dec 2020 and 13 Dec2020 are missing. However, Symptom log for dates 09 Dec 2020 and 14 Dec2020 are repeated twice. Please update the CRF to reflect correct dates for missing Symptom log' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 18:06:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:31:23
User entered 'SYMPTOMS STARTED 15-NOV, ILLNESS VISIT OCCURED ON 18-NOV. POSITIVE ALERT ON 23-NOV. PATIENT WITH RECENT TRAVEL out of state' reason for change: Data Entry Error	Nathan Cortez (b) (4)	23 Nov 2020 16:45:14
User entered 'SYMPTOMS STARTED 15-NOV, ILLNESS VISIT OCCURED ON 18-NOV. POSITIVE ALERT ON 23-NOV. Patient with recent travel to Mexico.' reason for change: Data Entry Error	Nathan Cortez (b) (4)	23 Nov 2020 16:29:17
User entered 'Symptoms started 15-NOV, Illness visit occurred on 18-Nov. Positive alert on 23-Nov.'	Nathan Cortez (b) (4)	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 16:33:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 16:27:51

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41



US3292320

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:33:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.	(b) (4)	09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'Per DM CLR: Please review and update AE term to reflect the medical condition/diagnosis instead of the causative agent. Please reconcile with Con Med eCRF as applicable. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 13:58:26
Query 'Per DM CLR: Please review and update AE term to reflect the medical condition/diagnosis instead of the causative agent. Please reconcile with Con Med eCRF as applicable. ' answered with 'AE term updated EDC query resolution' (Site from DM).	(b) (4)	18 Feb 2021 17:38:08
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Nasopharyngitis, LLT: Common cold - version MedDRA\23.0.	Coder Import (b) (4)	18 Feb 2021 17:32:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Feb 2021 17:32:53
Data point term sent to Coder	System	18 Feb 2021 17:32:19
Coding entries removed.	(b) (4), (b) (6)	18 Feb 2021 17:31:53
User entered 'Common Cold' reason for change: Data Entry Error	(b) (4)	18 Feb 2021 17:31:53
User opened query 'Per DM CLR: Please review and update AE term to reflect the medical condition/diagnosis instead of the causative agent. Please reconcile with Con Med eCRF as applicable. ' (Site from DM).	(b) (4)	25 Jan 2021 00:19:42
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Rhinoviral infections, PT: Rhinovirus infection, LLT: Rhinovirus infection - version MedDRA\23.0.	Coder Import (b) (4)	31 Dec 2020 19:18:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Dec 2020 19:18:40
Data point term sent to Coder	System	31 Dec 2020 19:18:09

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Rhinovirus'	Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '15 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
User entered empty.	System	31 Dec 2020 19:17:25



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**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '7 Dec 2020'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
User entered empty.	System	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

US3292320

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:33:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

US3292320

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:33:11

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

US3292320

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:33:11

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25



US3292320

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:33:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:33:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:33:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

US3292320

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:33:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

US3292320

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:33:11

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25



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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:33:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'Not Related (NOT RELATED)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'Not Related (NOT RELATED)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

US3292320

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:33:11

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	31 Dec 2020 19:17:31
User entered '1' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 19:17:31
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	31 Dec 2020 19:17:25
User entered '0'	Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:33:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

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**Generated On: 09 Jun 2021 16:33:11**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

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[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 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25



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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
DataPoint Verified.		09 Apr 2021 18:30:12
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
User entered '0'	System	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41
User entered 'I'	System	31 Dec 2020 19:17:25

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:41

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**Folder: Adverse Events**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.	(b) (4)	09 Apr 2021 18:31:58
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth infection, LLT: Tooth infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 00:35:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 00:35:45
Data point term sent to Coder	System	08 Mar 2021 20:24:41
Datapoint queued for coding (5294529).	System	08 Mar 2021 20:23:50
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:13:48
User entered 'L25 tooth infection' reason for change:	Gerardo Pena (b) (4)	17 Feb 2021 18:24:07
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 18:23:53
User entered 'bone infection'	Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

US3292320

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30



**US3292320**

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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 13:13:44
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

US3292320

Folder: Adverse Events

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Generated On: 09 Jun 2021 16:33:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '19 Jan 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

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**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
User entered empty.	System	17 Feb 2021 18:23:30

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.	(b) (4)	09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

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**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '4 Feb 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
User entered empty.	System	17 Feb 2021 18:23:30



US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.	(b) (4)	09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30



US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.	(b) (4)	09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30



US3292320

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User closed query 'Per CDM - RQ: Response noted "Updated". However update is not obvious please provide location of update such as log line number.' (Site from DM).		02 Apr 2021 12:31:33
Query 'Per CDM - RQ: Response noted "Updated". However update is not obvious please provide location of update such as log line number.' answered with 'updated clindimycin' (Site from DM).	Antonio Gutierrez (b) (4)	01 Apr 2021 18:24:12
User opened query 'Per CDM - RQ: Response noted "Updated". However update is not obvious please provide location of update such as log line number.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:28:08
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.		22 Mar 2021 09:28:08
' (Site from DM).		
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.	Kristy Trevino (b) (4)	17 Mar 2021 21:53:24
' answered with 'Concomitant medication added ' (Site from DM).	(b) (4)	
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.	(b) (4), (b) (6)	02 Mar 2021 05:19:08
' (Site from DM).		
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'I'	(b) (4)	
	Gerardo Pena (b) (4)	17 Feb 2021 18:23:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:33:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

[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 13:13:44
DataPoint Verified.	(b) (4)	09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
DataPoint Verified.		09 Apr 2021 18:31:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:13:48
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Feb 2021 18:23:30

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
User entered '0'	System	17 Feb 2021 18:23:30

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44
User entered 'I'	System	17 Feb 2021 18:23:30

**US3292320**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 16:33:11**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:13:44



US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:33:11

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:34
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User closed query 'Per hospital discharge summary, subject was prescribed Cyclobenzaprine and Methylprednisolone. Please update Con Med Log.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:11:12
User closed query 'Per ETRTR: Please confirm medication dosed for SAE "Right Hip Labrum Tear", thanks' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:11:09
Query 'Per hospital discharge summary, subject was prescribed Cyclobenzaprine and Methylprednisolone. Please update Con Med Log.' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4)	29 Oct 2020 16:35:28
User opened query 'Per hospital discharge summary, subject was prescribed Cyclobenzaprine and Methylprednisolone. Please update Con Med Log.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 18:43:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:17
Query 'Per ETRTR: Please confirm medication dosed for SAE "Right Hip Labrum Tear", thanks' answered with 'MEDICATION CONFIRMED IN ESOURCE AND CONMED LOG' (Site from CRA).	Victoria Hernandez (b) (4)	28 Sep 2020 18:33:23
User opened query 'Per ETRTR: Please confirm medication dosed for SAE "Right Hip Labrum Tear", thanks' (Site from CRA).	(b) (4), (b) (6)	27 Sep 2020 19:33:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 19:33:58

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:33:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:57:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:33:39
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 20:33:39
Data point term sent to Coder	System	23 Sep 2020 15:46:06
Coding entries removed.	Victoria Hernandez (b) (4) (b) (4)	23 Sep 2020 15:45:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:54:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:54:32
Data point term sent to Coder	System	27 Aug 2020 19:35:36
User entered 'Aspirin'	(b) (4), (b) (6)	27 Aug 2020 19:35:25

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:33:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:57:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	23 Sep 2020 15:44:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:35:25

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:33:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 18:10:46
User closed query 'Per source, subject has been taking Atorvastatin since 2018. Please update conmed list and also medical history conditions for hypercholesterolemia, if appropriate.' (Site from CRA).		06 Nov 2020 19:11:55
Query 'Per source, subject has been taking Atorvastatin since 2018. Please update conmed list and also medical history conditions for hypercholesterolemia, if appropriate.' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4)	29 Oct 2020 16:30:58
User opened query 'Per source, subject has been taking Atorvastatin since 2018. Please update conmed list and also medical history conditions for hypercholesterolemia, if appropriate.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 21:03:44
DataPoint Verified.		22 Oct 2020 20:57:44
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	23 Sep 2020 15:45:20
User entered 'preventative heart health' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	23 Sep 2020 15:45:15
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 10:55:52
User entered 'blood thinner'		27 Aug 2020 19:35:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered '81'	(b) (4), (b) (6)	27 Aug 2020 19:35:25

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:33:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 19:35:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:33:11**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User entered empty.		27 Aug 2020 19:35:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'other (OTHER)'	(b) (4), (b) (6)	27 Aug 2020 19:35:25



**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:33:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'BIW'	(b) (4), (b) (6)	27 Aug 2020 19:35:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User entered 'Oral (ORAL)'		27 Aug 2020 19:35:25

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:33:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User entered empty.		27 Aug 2020 19:35:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'un UNK 2019'	(b) (4), (b) (6)	27 Aug 2020 19:35:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 19:35:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 19:35:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:33:11**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:35:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 19:35:25



**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:35:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:35:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:35:25

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:33:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 16:47:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:16:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:16:12
Data point term sent to Coder	System	09 Nov 2020 21:47:27
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug. ' (Site from System).	System	09 Nov 2020 21:46:53
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug. ' answered with 'Updated' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 21:46:53
DataPoint Un-verified.		09 Nov 2020 21:46:43
User entered 'MOTRIN (ibuprofen)' reason for change: Per Query Resolution		09 Nov 2020 21:46:43
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug. ' (Site from System).	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:04:33
Data point term sent to Coder	System	29 Oct 2020 16:32:14
Coding entries removed.	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:31:33
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:33:11

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 12:13:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 12:13:43
Data point term sent to Coder	System	23 Sep 2020 15:52:29
Data point term sent to Coder	System	23 Sep 2020 15:47:09
Coding entries removed.	Victoria Hernandez (b) (4) (b) (4)	23 Sep 2020 15:46:56
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, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:46:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:46:42
Data point term sent to Coder	System	23 Sep 2020 15:46:07
Coding entries removed.	Victoria Hernandez (b) (4) (b) (4)	23 Sep 2020 15:45:56
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, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:54:34

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:33:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	27 Aug 2020 19:54:34
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	27 Aug 2020 19:36:38
User entered 'motrin'	(b) (4), (b) (6)	27 Aug 2020 19:35:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User entered 'No (N)'		27 Aug 2020 19:35:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:33:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
Query 'Please provide updated indication to con med source. ' canceled (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:59:14
User opened query 'Please provide updated indication to con med source. ' (Site from CRA). DataPoint Un-verified.		20 Apr 2021 16:42:54
DataPoint Verified.		19 Apr 2021 16:47:34
User closed query 'Source does not specify OA pain. Please considering updating source.' (Site from CRA).		19 Apr 2021 16:47:18
Query 'Source does not specify OA pain. Please considering updating source.' answered with 'updated' (Site from CRA). DataPoint Un-verified.	Dawn Killian (b) (4)	16 Nov 2020 02:44:30
User entered 'generalized OSTEOARTHRITIS PAIN' reason for change: Data Entry Error User opened query 'Source does not specify OA pain. Please considering updating source.' (Site from CRA). DataPoint Verified.	Dawn Killian (b) (4)	16 Nov 2020 02:44:29
User closed query 'Per DM CLR: Please note that there is no MH that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the MH eCRF if appropriate.' (Site from DM). User closed query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	Dawn Killian (b) (4)	29 Oct 2020 16:31:39
User entered 'OSTEOARTHRITIS PAIN' reason for change: Data Entry Error Query 'Per DM CLR: Please note that there is no MH that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the MH eCRF if appropriate.' answered with 'UPDATED' (Site from DM).	Dawn Killian (b) (4)	29 Oct 2020 16:31:33
	Dawn Killian (b) (4)	29 Oct 2020 16:31:33
	(b) (4), (b) (6)	29 Oct 2020 16:31:33
	(b) (4), (b) (6)	22 Oct 2020 20:58:26
		22 Oct 2020 20:57:44
		07 Oct 2020 13:09:12
		07 Oct 2020 13:09:10
	Victoria Hernandez (b) (4)	23 Sep 2020 15:52:08
	(b) (4)	23 Sep 2020 15:47:01
	Victoria Hernandez (b) (4)	23 Sep 2020 15:47:01
	(b) (4)	

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:33:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'GENERALIZED OSTEOARTHRITIS PAIN' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	23 Sep 2020 15:46:56
Query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	23 Sep 2020 15:46:02
User entered 'GENERALIZED PAIN' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	23 Sep 2020 15:45:56
User opened query 'Per DM CLR: Please note that there is no MH that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the MH eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 04:02:51
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).		23 Sep 2020 04:00:13
User entered 'pain'		27 Aug 2020 19:35:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered '200'	(b) (4), (b) (6)	27 Aug 2020 19:35:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:33:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 19:35:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:33:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:35:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'as needed (PRN)'	(b) (4), (b) (6)	27 Aug 2020 19:35:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:33:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:35:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 19:35:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:33:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:35:55



US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:33:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:44:32
Query 'Per con med source, start date is UN UNK 1990. Please review and reconcile. ' canceled (Site from CRA).		20 Apr 2021 16:44:26
User opened query 'Per con med source, start date is UN UNK 1990. Please review and reconcile. ' (Site from CRA).		19 Apr 2021 16:48:04
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of SPINAL OSTEOARTHRITIS. Please review and reconcile Con Med and Med History start dates as appropriate.		05 Jan 2021 08:30:01
' (Site from DM).		
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of SPINAL OSTEOARTHRITIS. Please review and reconcile Con Med and Med History start dates as appropriate.	Nathan Cortez (b) (4)	31 Dec 2020 18:57:42
' answered with 'Updated' (Site from DM).		
DataPoint Un-verified.	Nathan Cortez (b) (4)	31 Dec 2020 18:57:36
User entered 'UN UNK 2008' reason for change:	Nathan Cortez (b) (4)	31 Dec 2020 18:57:36
Data Entry Error		
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of SPINAL OSTEOARTHRITIS. Please review and reconcile Con Med and Med History start dates as appropriate.	(b) (4), (b) (6)	17 Dec 2020 19:15:49
' (Site from DM).		
DataPoint Verified.		22 Oct 2020 20:57:44
User entered 'un UNK 1990'		27 Aug 2020 19:35:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 19:35:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 19:35:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:33:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:35:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:33:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 19:35:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:35:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:35:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:35:55



US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:33:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:54:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:54:35
Data point term sent to Coder	System	27 Aug 2020 19:36:39
User entered 'amlodipine'	(b) (4), (b) (6)	27 Aug 2020 19:36:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 19:36:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'hypertension'	(b) (4), (b) (6)	27 Aug 2020 19:36:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User entered '10'		27 Aug 2020 19:36:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 19:36:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:36:25

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:33:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:57:44
User entered 'twice daily (BID)' reason for change:	Victoria Hernandez (b) (4)	23 Sep 2020 15:47:25
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	(b) (4), (b) (6)	27 Aug 2020 19:36:25

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:33:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).		07 Oct 2020 13:09:56
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	23 Sep 2020 15:47:35
	(b) (4)	
User entered empty; reason for change Data Entry Error	Victoria Hernandez (b) (4)	23 Sep 2020 15:47:25
	(b) (4)	
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 10:55:12
User entered 'BIW'		27 Aug 2020 19:36:25



**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User entered 'Oral (ORAL)'		27 Aug 2020 19:36:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User entered empty.		27 Aug 2020 19:36:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'un UNK 2018'	(b) (4), (b) (6)	27 Aug 2020 19:36:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 19:36:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 19:36:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User entered empty.		27 Aug 2020 19:36:25

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:33:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 19:36:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Sep 2020 15:47:25
User entered empty.	System	27 Aug 2020 19:36:25



**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	23 Sep 2020 15:47:25
User entered empty.	System	27 Aug 2020 19:36:25

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 15:47:25
User entered empty.	System	27 Aug 2020 19:36:25

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:33:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 00:55:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Nov 2020 00:55:37
Data point term sent to Coder	System	29 Oct 2020 16:44:40
Data point term sent to Coder	System	29 Oct 2020 16:34:18
Coding entries removed.	Dawn Killian (b) (4)	29 Oct 2020 16:33:57
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Sep 2020 23:04:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Sep 2020 23:04:40
Data point term sent to Coder	System	23 Sep 2020 15:51:25
Coding entries removed.	Victoria Hernandez (b) (4)	23 Sep 2020 15:50:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:54:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:54:41
Data point term sent to Coder	System	27 Aug 2020 19:37:48
User entered 'gabapentin'	(b) (4), (b) (6)	27 Aug 2020 19:37:03

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User entered 'No (N)'		27 Aug 2020 19:37:03

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:33:11

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Please provide updated indication in Con med source.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 14:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
Query 'Please provide updated indication in Con med source.' answered with 'updated ' (Site from CRA).	(b) (4)	
DataPoint Verified.	Antonio Gutierrez (b) (4)	21 Apr 2021 22:15:32
	(b) (4), (b) (6)	20 Apr 2021 16:44:55
User opened query 'Please provide updated indication in Con med source.' (Site from CRA).		19 Apr 2021 16:48:42
User closed query 'Please update source to include "spinal OA" under condition.' (Site from CRA).		16 Nov 2020 02:44:49
User entered 'spinal OSTEOARTHRITIS' reason for change: Data Entry Error	Dawn Killian (b) (4)	29 Oct 2020 16:43:44
Query 'Please update source to include "spinal OA" under condition.' answered with 'updated' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Dawn Killian (b) (4)	29 Oct 2020 16:34:06
	(b) (4)	
User entered 'generalized OSTEOARTHRITIS' reason for change: Data Entry Error	Dawn Killian (b) (4)	29 Oct 2020 16:33:57
User opened query 'Please update source to include "spinal OA" under condition.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:59:19
		22 Oct 2020 20:57:44
User closed query 'Per DM CLR: Please update the indication and provide the location and laterality of the OSTEOARTHRITIS (e.g. knee; bilateral, left, right). Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).		07 Oct 2020 13:10:28
Query 'Per DM CLR: Please update the indication and provide the location and laterality of the OSTEOARTHRITIS (e.g. knee; bilateral, left, right). Review and update indication and ensure to update MH eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	23 Sep 2020 15:50:40
User entered 'SPINE OSTEOARTHRITIS' reason for change: Data Entry Error	(b) (4)	
	Victoria Hernandez (b) (4)	23 Sep 2020 15:50:26

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:33:11

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication and provide the location and laterality of the OSTEOARTHRITIS (e.g. knee; bilateral, left, right). Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM). User entered 'osteoarthritis'	(b) (4), (b) (6)	22 Sep 2020 12:13:37
		27 Aug 2020 19:37:03

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered '500'	(b) (4), (b) (6)	27 Aug 2020 19:37:03

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 19:37:03



US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:33:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User entered empty.		27 Aug 2020 19:37:03

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'as needed (PRN)'	(b) (4), (b) (6)	27 Aug 2020 19:37:03

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:33:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:37:03

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 19:37:03

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:37:03

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:57:44
User entered 'un UNK 2008'		27 Aug 2020 19:37:03

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 19:37:03

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 19:37:03



**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:37:03

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	22 Oct 2020 20:57:44
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 19:37:03

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:37:03

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:37:03

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:37:03

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	22 Apr 2021 07:17:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Apr 2021 07:17:55
Data point term sent to Coder Coding entries removed.	System Antonio Gutierrez (b) (4)	21 Apr 2021 22:18:45 21 Apr 2021 22:17:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:49:20
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 08:46:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 08:46:53
Data point term sent to Coder Coding entries removed.	System Dawn Killian (b) (4)	13 Apr 2021 20:13:27 13 Apr 2021 20:13:00
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 22:08:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 22:08:28
Data point term sent to Coder	System	05 Nov 2020 22:07:20

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
Data point term sent to Coder	System	31 Aug 2020 19:50:19
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	31 Aug 2020 19:49:32
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Aug 2020 11:56:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Aug 2020 11:56:32
Data point term sent to Coder	System	27 Aug 2020 19:38:51
User entered 'testosterone treatment'	(b) (4), (b) (6)	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:50:57
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4) (b) (4)	31 Aug 2020 19:49:32
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 19:37:51



US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:49:22
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4) (b) (4)	31 Aug 2020 19:49:32
User entered 'low testosterone'	(b) (4), (b) (6)	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per con med source, dose is 100' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 16:02:36
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:02:34
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
Query 'Per con med source, dose is 100' answered with 'updated as per source ' (Site from CRA).	(b) (4)	
User entered '100' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	21 Apr 2021 22:18:42
User opened query 'Per con med source, dose is 100' (Site from CRA).	Antonio Gutierrez (b) (4)	21 Apr 2021 22:17:47
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 16:49:39
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. Please review and update accordingly' answered with 'updated' (Site from DM).		02 Apr 2021 10:17:59
User entered 'UNK' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	01 Apr 2021 17:34:54
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 17:34:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Jan 2021 08:07:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Nov 2020 16:24:57
DataPoint inactivated with code reason code Data not required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Dawn Killian (b) (4)	31 Aug 2020 19:49:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:37:57
	System	27 Aug 2020 19:37:51
	(b) (4), (b) (6)	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response/ update noted however, "Dose unit" should be recorded as "UNK" if data is 'unknown'. Please update as appropriate. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:03:15
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 16:02:43
Query 'Per CDM: Response/ update noted however, "Dose unit" should be recorded as "UNK" if data is 'unknown'. Please update as appropriate. Thank you.'	(b) (4)	22 Apr 2021 15:51:35
answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	21 Apr 2021 22:18:32
User opened query 'Per CDM: Response/ update noted however, "Dose unit" should be recorded as "UNK" if data is 'unknown'. Please update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:41:24
User closed query 'Per CDM: Per CCG's Dose Unit should be "UNK" if data is not available. Please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:41:24
Query 'Per CDM: Per CCG's Dose Unit should be "UNK" if data is not available. Please review and update accordingly ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	13 Apr 2021 20:12:49
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4)	13 Apr 2021 20:12:44
User opened query 'Per CDM: Per CCG's Dose Unit should be "UNK" if data is not available. Please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 10:20:11
Query 'Per CDM: Per CCG's Dose Unit per administration should be "UNK" if data is not available. Please review and update accordingly ' canceled (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 10:19:52
User opened query 'Per CDM: Per CCG's Dose Unit per administration should be "UNK" if data is not available. Please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 10:19:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 16:24:59
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	31 Aug 2020 19:49:32
	(b) (4)	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:33:11**

[Dose unit](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 19:38:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 19:37:51
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User closed query 'Per con med source, Dose unit is "mg/mL"' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 16:02:47
DataPoint Verified.		22 Apr 2021 16:02:46
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
Query 'Per con med source, Dose unit is "mg/mL"' answered with 'updated' (Site from CRA).	(b) (4)	
	Antonio Gutierrez (b) (4)	21 Apr 2021 22:18:20
User entered 'mg/mL' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	21 Apr 2021 22:17:47
User opened query 'Per con med source, Dose unit is "mg/mL"' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:50:16
User entered 'UNK' reason for change: Data Entry Error	Dawn Killian (b) (4)	13 Apr 2021 20:12:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	31 Aug 2020 19:49:32
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:50:19
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4) (b) (4)	31 Aug 2020 19:49:32
User entered 'every week (QS)'	(b) (4), (b) (6)	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:50:21
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4) (b) (4)	31 Aug 2020 19:49:32
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response/ update noted however, "Route of administration" should be recorded as "UNK" if data is 'unknown'. Please update as appropriate. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 06:29:48
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 16:02:54
Query 'Per CDM: Response/ update noted however, "Route of administration" should be recorded as "UNK" if data is 'unknown'. Please update as appropriate. Thank you.' answered with 'updated' (Site from DM). DataPoint Un-verified.	Antonio Gutierrez (b) (4)	21 Apr 2021 22:18:12
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Per Query Resolution DataPoint Verified.	Antonio Gutierrez (b) (4)	21 Apr 2021 22:17:47
User opened query 'Per CDM: Response/ update noted however, "Route of administration" should be recorded as "UNK" if data is 'unknown'. Please update as appropriate. Thank you.' (Site from DM). User closed query 'Per CDM: Per CCG's Route of administration should be "UNK" if data is not available. Please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 16:50:25
Query 'Per CDM: Per CCG's Route of administration should be "UNK" if data is not available. Please review and update accordingly ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	13 Apr 2021 20:13:07
User entered 'Other (OTHER)' reason for change: Data Entry Error	Dawn Killian (b) (4)	13 Apr 2021 20:13:00
User opened query 'Per CDM: Per CCG's Route of administration should be "UNK" if data is not available. Please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 10:19:44
User closed query 'Data is required. Please complete.' (Site from System).		09 Nov 2020 16:25:02
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	31 Aug 2020 19:49:32
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 19:38:05
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 19:37:51
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User closed query 'Per con med source, route is IM.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 16:03:02
DataPoint Verified.	(b) (4)	22 Apr 2021 16:03:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
Query 'Per con med source, route is IM.' answered with 'updated as per source ' (Site from CRA).	(b) (4)	
User entered empty; reason for change Data Entry Error	Antonio Gutierrez (b) (4)	21 Apr 2021 22:18:07
User opened query 'Per con med source, route is IM.' (Site from CRA).	Antonio Gutierrez (b) (4)	21 Apr 2021 22:17:47
User entered 'UNK' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 16:50:36
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	13 Apr 2021 20:13:00
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
	(b) (4)	
	Dawn Killian (b) (4)	31 Aug 2020 19:49:32
	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 19:37:51
	(b) (4), (b) (6)	

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per son med source, start date is UN UNK 2008. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:03:06
		22 Apr 2021 16:03:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
	(b) (4)	
Query 'Per son med source, start date is UN UNK 2008. ' answered with 'updated as per source ' (Site from CRA).	Antonio Gutierrez (b) (4)	21 Apr 2021 22:17:58
User entered 'UN UNK 2008' reason for change: Per Antonio Gutierrez (b) (4)		21 Apr 2021 22:17:47
Query Resolution		
User opened query 'Per son med source, start date is UN UNK 2008. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:50:49
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of LOW TESTOSTERONE. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).		05 Jan 2021 08:31:25
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of LOW TESTOSTERONE. Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'Updated' (Site from DM).	Nathan Cortez (b) (4)	31 Dec 2020 20:29:58
User entered 'UN UNK 2019' reason for change: Data Entry Error	Nathan Cortez (b) (4)	31 Dec 2020 20:29:53
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of LOW TESTOSTERONE. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 19:16:10
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	31 Aug 2020 19:49:32
	(b) (4)	
User entered 'un UNK 2008'	(b) (4), (b) (6)	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:50:50
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4) (b) (4)	31 Aug 2020 19:49:32
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:50:52
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4) (b) (4)	31 Aug 2020 19:49:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:50:53
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4) (b) (4)	31 Aug 2020 19:49:32
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:50:54
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4) (b) (4)	31 Aug 2020 19:49:32
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	31 Aug 2020 19:49:32
User entered 'l'	System	27 Aug 2020 19:37:51



**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	31 Aug 2020 19:49:32
User entered 'I'	System	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:33:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Antonio Gutierrez (b) (4)	05 Nov 2020 22:07:15
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	31 Aug 2020 19:49:32
User entered '803 (803)'	System	27 Aug 2020 19:37:51

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:33:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 16:32:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 16:32:19
Data point term sent to Coder	System	29 Oct 2020 16:31:10
User entered 'atorvastatin'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:33:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:33:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 16:51:15
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.		17 Dec 2020 19:17:03
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.		17 Dec 2020 19:16:28
' (Site from DM).		
User entered 'hypercholesterolemia'	Dawn Killian (b) (4)	29 Oct 2020 16:30:44
	(b) (4)	

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:33:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered '30'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:33:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered 'mg (mg)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:33:11**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered empty.	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44



US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:33:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered 'once daily (QD)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:33:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered empty.	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:33:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered 'Oral (ORAL)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:33:11**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered empty.	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:33:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered 'UN UNK 2018'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered '0'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:33:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:33:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered empty.	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44



US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:33:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:30:44

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Oct 2020 16:30:44

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Oct 2020 16:30:44

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 16:30:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:33:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 14:10:25
Query 'Please confirm spelling' canceled (Site from CRA).		20 Apr 2021 14:10:24
User opened query 'Please confirm spelling' (Site from CRA).		19 Apr 2021 16:51:30
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 10:56:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 10:56:32
Data point term sent to Coder	System	05 Nov 2020 00:01:27
Coding entries removed.	Antonio Gutierrez (b) (4)	05 Nov 2020 00:01:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Oct 2020 16:27:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Oct 2020 16:27:54
Data point term sent to Coder	System	29 Oct 2020 16:38:25
User entered 'methylprednisolone'	Dawn Killian (b) (4)	29 Oct 2020 16:37:32
	(b) (4)	

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:33:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:51:43
User entered 'No (N)'	Dawn Killian (b) (4)	29 Oct 2020 16:37:32

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:33:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:44
User entered 'TEAR IN Left HIP LABRUIM' reason for change: New Information	Antonio Gutierrez (b) (4)	05 Nov 2020 00:01:02
User entered 'tear in right hip labruim'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:37:32

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:51:46
User entered '4'	Dawn Killian (b) (4)	29 Oct 2020 16:37:32



**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:51:48
User entered 'mg (mg)'	Dawn Killian (b) (4)	29 Oct 2020 16:37:32

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:33:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:51:50
User entered empty.	Dawn Killian (b) (4)	29 Oct 2020 16:37:32

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:33:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:10
User entered 'once daily (QD)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:37:32

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:33:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:52:14
User entered empty.	Dawn Killian (b) (4)	29 Oct 2020 16:37:32

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:52:15
User entered 'Oral (ORAL)'	Dawn Killian (b) (4)	29 Oct 2020 16:37:32

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:33:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:52:16
User entered empty.	Dawn Killian (b) (4)	29 Oct 2020 16:37:32

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:52:19
User entered '05 Sep 2020'	Dawn Killian (b) (4)	29 Oct 2020 16:37:32

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:52:20
User entered '0'	Dawn Killian (b) (4)	29 Oct 2020 16:37:32



US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:33:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 16:52:21
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		02 Apr 2021 10:20:56
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	01 Apr 2021 18:00:07
User entered 'No (N)' reason for change: New Information	Antonio Gutierrez (b) (4)	01 Apr 2021 17:59:27
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 00:18:59
User entered 'Yes (Y)'	Dawn Killian (b) (4)	29 Oct 2020 16:37:32
	(b) (4)	

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:33:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:23
User entered '10 Sep 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	01 Apr 2021 17:59:27
User entered empty.	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:37:32

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:52:25
User entered 'No (N)'	Dawn Killian (b) (4)	29 Oct 2020 16:37:32

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User entered 'I'	System	29 Oct 2020 16:37:32

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User entered 'I'	System	29 Oct 2020 16:37:32

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:47
User entered '804 (804)'	System	29 Oct 2020 16:37:32

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:33:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User closed query 'Please provide spelling update to con med source. ' (Site from CRA).	(b) (4)	23 Apr 2021 14:26:22
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
Query 'Please provide spelling update to con med source. ' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	21 Apr 2021 22:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:46:43
User opened query 'Please provide spelling update to con med source. ' (Site from CRA).	(b) (4)	19 Apr 2021 16:53:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 22:27:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 22:27:28
Data point term sent to Coder	System	05 Nov 2020 00:01:27
Coding entries removed.	Antonio Gutierrez (b) (4)	05 Nov 2020 00:01:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 22:10:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 22:10:52
Data point term sent to Coder	System	29 Oct 2020 16:39:28
User entered 'FLEXeril' reason for change: Data Entry Error	Dawn Killian (b) (4)	29 Oct 2020 16:38:49

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:33:11

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'flexoril'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:38:34



US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:33:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:53:30
User entered 'No (N)'	Dawn Killian (b) (4)	29 Oct 2020 16:38:34

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:33:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User closed query 'Per con med source, Indication is "Right side hip trauma". Please review and reconcile. ' (Site from CRA).		23 Apr 2021 14:26:17
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:51:35
Query 'Per con med source, Indication is "Right side hip trauma". Please review and reconcile. ' answered with 'reconciled ' (Site from CRA).	Antonio Gutierrez (b) (4)	21 Apr 2021 22:20:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:46:45
User opened query 'Per con med source, Indication is "Right side hip trauma". Please review and reconcile. ' (Site from CRA).		19 Apr 2021 16:53:59
User entered 'TEAR IN Left HIP LABRIUM' reason for change: New Information	Antonio Gutierrez (b) (4)	05 Nov 2020 00:01:20
User entered 'tear in right hip labrium'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:38:34

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:33:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:02
User entered '10'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:38:34

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:33:11**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:03
User entered 'mg (mg)'	Dawn Killian (b) (4)	29 Oct 2020 16:38:34

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:33:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User entered empty.	Dawn Killian (b) (4)	29 Oct 2020 16:38:34

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:33:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:06
User entered 'as needed (PRN)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:38:34

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:33:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:08
User entered empty.	Dawn Killian (b) (4)	29 Oct 2020 16:38:34

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:33:11**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:11
User entered 'Oral (ORAL)'	Dawn Killian (b) (4)	29 Oct 2020 16:38:34



**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:33:11**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:13
User entered empty.	Dawn Killian (b) (4)	29 Oct 2020 16:38:34

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:33:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:10
User entered '05 Sep 2020'	Dawn Killian (b) (4)	29 Oct 2020 16:38:34

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:15
User entered '0'	Dawn Killian (b) (4)	29 Oct 2020 16:38:34

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:33:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:20
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		02 Apr 2021 10:21:10
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	01 Apr 2021 18:21:50
User entered 'No (N)' reason for change: New Information	Antonio Gutierrez (b) (4)	01 Apr 2021 18:19:34
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 00:19:11
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:38:34

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:33:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:23
User entered '08 Sep 2020' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	01 Apr 2021 18:19:34
User entered empty.	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:38:34

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:33:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:24
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:38:34

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:33:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User entered empty.	System	29 Oct 2020 16:38:34

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User entered empty.	System	29 Oct 2020 16:38:34



**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:50
User entered empty.	System	29 Oct 2020 16:38:34

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:33:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 13:46:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 13:46:17
Data point term sent to Coder	System	05 Nov 2020 00:02:28
Coding entries removed.	Antonio Gutierrez (b) (4)	05 Nov 2020 00:01:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:43:44
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 21:43:44
Data point term sent to Coder	System	29 Oct 2020 16:40:30
User entered 'cyclobenzaprine'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:39:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:33:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:20
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:39:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:33:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:20
User entered 'TEAR IN Left HIP LABRUM' reason for change: New Information	Antonio Gutierrez (b) (4)	05 Nov 2020 00:01:38
User entered 'tear in right hip labrum'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:39:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:33:11**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:55:20
User entered '10'	Dawn Killian (b) (4)	29 Oct 2020 16:39:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:33:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:20
User entered 'mg (mg)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:39:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:33:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:55:20
User entered empty.	Dawn Killian (b) (4)	29 Oct 2020 16:39:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:33:11**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:20
User entered 'as needed (PRN)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:39:55



US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:33:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:55:20
User entered empty.	Dawn Killian (b) (4)	29 Oct 2020 16:39:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:33:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:20
User entered 'Oral (ORAL)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:39:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:33:11**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:20
User entered empty.	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:39:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:55:20
User entered '05 Sep 2020'	Dawn Killian (b) (4)	29 Oct 2020 16:39:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:55:20
User entered '0'	Dawn Killian (b) (4)	29 Oct 2020 16:39:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:33:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:55:20
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		02 Apr 2021 10:21:19
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	01 Apr 2021 18:22:35
User entered 'No (N)' reason for change: New Information	Antonio Gutierrez (b) (4)	01 Apr 2021 18:22:11
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 00:19:21
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	29 Oct 2020 16:39:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:33:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User closed query 'Per source, Stop date is 08Sep2021. Please review and reconcile. ' (Site from CRA).		23 Apr 2021 14:26:45
DataPoint Verified.		23 Apr 2021 14:26:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
Query 'Per source, Stop date is 08Sep2021. Please review and reconcile. ' answered with 'corrected to 2020' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	21 Apr 2021 22:21:21
	(b) (4), (b) (6)	19 Apr 2021 16:55:29
DataPoint Verified.		19 Apr 2021 16:55:20
User opened query 'Per source, Stop date is 08Sep2021. Please review and reconcile. ' (Site from CRA).		19 Apr 2021 16:55:12
User entered '08 Sep 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	01 Apr 2021 18:22:11
User entered empty.	Dawn Killian (b) (4)	29 Oct 2020 16:39:55
	(b) (4)	

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:33:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:55:14
User entered 'No (N)'	Dawn Killian (b) (4)	29 Oct 2020 16:39:55



**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:33:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User entered empty.	System	29 Oct 2020 16:39:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User entered empty.	System	29 Oct 2020 16:39:55

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:53
User entered empty.	System	29 Oct 2020 16:39:55

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:33:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.		23 Apr 2021 14:27:13
User closed query 'Please provide medication to Con med source. ' (Site from CRA).		23 Apr 2021 14:27:08
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
Query 'Please provide medication to Con med source. ' answered with 'added to source ' (Site from CRA).	Antonio Gutierrez (b) (4)	21 Apr 2021 22:22:47
User opened query 'Please provide medication to Con med source. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:56:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 09:29:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 09:29:56
Data point term sent to Coder	System	01 Apr 2021 17:47:27
Coding entries removed.	Antonio Gutierrez (b) (4)	01 Apr 2021 17:47:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 21:52:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 21:52:51
Data point term sent to Coder	System	17 Mar 2021 21:51:45
User entered 'Clindamycin'	Kristy Trevino (b) (4)	17 Mar 2021 21:51:44

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:33:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User entered 'No (N)'	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Mar 2021 21:51:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:33:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.	(b) (4)	23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 12:28:13
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	01 Apr 2021 17:47:20
User entered 'L25 TOOTH INFECTION' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	01 Apr 2021 17:47:11
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:41:27
User entered 'Antibiotic'	Kristy Trevino (b) (4)	17 Mar 2021 21:51:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:33:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.		23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User entered '125'	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Mar 2021 21:51:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:33:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.	(b) (4)	23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User entered 'mg (mg)'	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Mar 2021 21:51:44



US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:33:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.	(b) (4)	23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Mar 2021 21:51:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:33:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.	(b) (4)	23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User entered 'three times daily (TID)'	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Mar 2021 21:51:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:33:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.	(b) (4)	23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Mar 2021 21:51:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:33:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.	(b) (4)	23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User entered 'Oral (ORAL)'	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Mar 2021 21:51:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:33:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.		23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Mar 2021 21:51:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:33:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.	(b) (4)	23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User entered '19 Jan 2021'	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Mar 2021 21:51:44

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:33:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.		23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User entered '0'	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Mar 2021 21:51:44

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:33:11**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.		23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User entered 'No (N)'	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Mar 2021 21:51:44



**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:33:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.		23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User entered '2 Feb 2021'	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Mar 2021 21:51:44

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:33:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
DataPoint Verified.	(b) (4)	23 Apr 2021 14:27:13
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
User entered 'No (N)'	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Mar 2021 21:51:44

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:33:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
User entered '3'	System	17 Mar 2021 21:51:44

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
User entered 'I'	System	17 Mar 2021 21:51:44

**US3292320**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:33:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:13:57
User entered '804 (804)'	System	17 Mar 2021 21:51:44

US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:33:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:34
DataPoint Verified.		19 Apr 2021 16:57:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Yes (Y)'	(b) (4) Antonio Gutierrez (b) (4)	05 Nov 2020 00:02:06

US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:33:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '2 Sep 2020'	(b) (4) Antonio Gutierrez (b) (4)	05 Nov 2020 00:03:54

US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:33:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:42:05
User closed query 'Per concomitant procedures source, procedure is "Lumbar/Hip MRI". Please review and reconcile. ' (Site from CRA).		20 Apr 2021 16:42:03
Query 'Per concomitant procedures source, procedure is "Lumbar/Hip MRI". Please review and reconcile. ' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4)	20 Apr 2021 16:09:48
Signature has been broken.	(b) (4)	
	Dawn Killian (b) (4)	20 Apr 2021 16:09:44
User entered 'LUMBAR/HIP MRI' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per concomitant procedures source, procedure is "Lumbar/Hip MRI". Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:58:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Lumbar/Hip MRI W & W/O'	(b) (4)	
	Antonio Gutierrez (b) (4)	05 Nov 2020 00:03:54



US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:33:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Adverse Event (AE)'	(b) (4) Antonio Gutierrez (b) (4)	05 Nov 2020 00:03:54

US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:33:11

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	05 Nov 2020 00:03:54

US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:33:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:38
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '30 Aug 2020'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:06:05

US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:33:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:38
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Catheter Placement'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:06:05

**US3292320**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:38
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'Adverse Event (AE)'	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:06:05

US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:33:11

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:57:38
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered empty.	(b) (4) Nathan Cortez (b) (4)	31 Dec 2020 19:06:05

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'USA-US072-2020-MRNA-1273-P301000003'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Yes (Y)'	System	23 Sep 2020 14:38:57



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Yes (Y)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Douglas'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Denham'	System	23 Sep 2020 14:38:57



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered '7940 Floyd Curl Drive'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'San Antonio'	System	23 Sep 2020 14:38:57

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:01:20
Reviewed for Safety.		05 Nov 2020 14:02:27
Un-reviewed for Safety.	System	14 Oct 2020 15:16:12
User entered empty.	System	14 Oct 2020 15:16:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:16:05
User entered 'Texas'	Victoria Hernandez (b) (4)	13 Oct 2020 20:46:47
	(b) (4)	

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.		23 Sep 2020 14:39:18
User entered '78229'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4)	14 Oct 2020 15:16:05
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:22
User entered 'US'	System	23 Sep 2020 14:39:25

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '5'	(b) (4)	04 Jan 2021 14:52:38
User entered '4'	System	06 Nov 2020 13:14:38
User entered '3'	System	05 Nov 2020 14:02:37
User entered '2'	System	14 Oct 2020 15:16:12
User entered '1'	System	23 Sep 2020 14:39:25

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'USA-US072-2020-MRNA-1273-P301000003'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.		23 Sep 2020 14:39:18
User entered 'Yes (Y)'	System	23 Sep 2020 14:38:57



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Yes (Y)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Douglas'	System	23 Sep 2020 14:38:57

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Denham'	System	23 Sep 2020 14:38:57



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered '7940 Floyd Curl Drive'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'San Antonio'	System	23 Sep 2020 14:38:57

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:01:20
Reviewed for Safety.		05 Nov 2020 14:02:27
Un-reviewed for Safety.	System	14 Oct 2020 15:16:12
User entered empty.	System	14 Oct 2020 15:16:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:16:05
User entered 'Texas'	Victoria Hernandez (b) (4)	13 Oct 2020 20:46:47
	(b) (4)	

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered '78229'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:05
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:22
User entered 'US'	System	23 Sep 2020 14:39:25

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '5'	(b) (4)	04 Jan 2021 14:52:38
User entered '4'	System	06 Nov 2020 13:14:38
User entered '3'	System	05 Nov 2020 14:02:37
User entered '2'	System	14 Oct 2020 15:16:12
User entered '1'	System	23 Sep 2020 14:39:25

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
User entered '23/Sep/2020 10:39'	System	23 Sep 2020 14:39:25

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:33:11

**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.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4)	14 Oct 2020 15:16:05
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:22
User entered 'l'		23 Sep 2020 14:39:25



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'USA-US072-2020-MRNA-1273-P301000003'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Yes (Y)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.		23 Sep 2020 14:39:18
User entered 'Yes (Y)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Douglas'	System	23 Sep 2020 14:38:57

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Denham'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered '7940 Floyd Curl Drive'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'San Antonio'	System	23 Sep 2020 14:38:57

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:01:20
Reviewed for Safety.		05 Nov 2020 14:02:27
Un-reviewed for Safety.	System	14 Oct 2020 15:16:12
User entered empty.	System	14 Oct 2020 15:16:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:16:05
User entered 'Texas'	Victoria Hernandez (b) (4)	13 Oct 2020 20:46:47
	(b) (4)	

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.		23 Sep 2020 14:39:18
User entered '78229'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:05
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:22
User entered 'US'	System	23 Sep 2020 14:39:25

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '5'	(b) (4)	04 Jan 2021 14:52:38
User entered '4'	System	06 Nov 2020 13:14:38
User entered '3'	System	05 Nov 2020 14:02:37
User entered '2'	System	14 Oct 2020 15:16:12
User entered '1'	System	23 Sep 2020 14:39:25



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '14/Oct/2020 11:16'	(b) (4) System	14 Oct 2020 15:16:12

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:33:11

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 14:02:27
User entered 'l'	(b) (4), (b) (6)	14 Oct 2020 15:16:12

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'USA-US072-2020-MRNA-1273-P301000003'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Yes (Y)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Yes (Y)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Douglas'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Denham'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered '7940 Floyd Curl Drive'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'San Antonio'	System	23 Sep 2020 14:38:57

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:01:20
Reviewed for Safety.		05 Nov 2020 14:02:27
Un-reviewed for Safety.	System	14 Oct 2020 15:16:12
User entered empty.	System	14 Oct 2020 15:16:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:16:05
User entered 'Texas'	Victoria Hernandez (b) (4)	13 Oct 2020 20:46:47
	(b) (4)	

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered '78229'	System	23 Sep 2020 14:38:57



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:05
DataPoint Verified.		02 Oct 2020 20:58:22
User entered 'US'	System	23 Sep 2020 14:39:25

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '5'	(b) (4)	04 Jan 2021 14:52:38
User entered '4'	System	06 Nov 2020 13:14:38
User entered '3'	System	05 Nov 2020 14:02:37
User entered '2'	System	14 Oct 2020 15:16:12
User entered '1'	System	23 Sep 2020 14:39:25

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '05/Nov/2020 09:02'	(b) (4) System	05 Nov 2020 14:02:37

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:33:11

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:49
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 13:14:29
User entered 'l'		05 Nov 2020 14:02:37

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'USA-US072-2020-MRNA-1273-P301000003'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Yes (Y)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Yes (Y)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Douglas'	System	23 Sep 2020 14:38:57

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Denham'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered '7940 Floyd Curl Drive'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'San Antonio'	System	23 Sep 2020 14:38:57



US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:01:20
Reviewed for Safety.		05 Nov 2020 14:02:27
Un-reviewed for Safety.	System	14 Oct 2020 15:16:12
User entered empty.	System	14 Oct 2020 15:16:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:16:05
User entered 'Texas'	Victoria Hernandez (b) (4)	13 Oct 2020 20:46:47
	(b) (4)	

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered '78229'	System	23 Sep 2020 14:38:57

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:05
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:22
User entered 'US'	System	23 Sep 2020 14:39:25

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '5'	(b) (4)	04 Jan 2021 14:52:38
User entered '4'	System	06 Nov 2020 13:14:38
User entered '3'	System	05 Nov 2020 14:02:37
User entered '2'	System	14 Oct 2020 15:16:12
User entered '1'	System	23 Sep 2020 14:39:25

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:33:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '06/Nov/2020 13:14'	(b) (4) System	06 Nov 2020 13:14:38

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:33:11

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4)	04 Jan 2021 14:52:29
User entered 'l'	(b) (4), (b) (6)	06 Nov 2020 13:14:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'USA-US072-2020-MRNA-1273-P301000003'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Yes (Y)'	System	23 Sep 2020 14:38:57



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Yes (Y)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:38:57
	System	

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'No (N)'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Douglas'	System	23 Sep 2020 14:38:57

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'Denham'	System	23 Sep 2020 14:38:57



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered '7940 Floyd Curl Drive'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	02 Oct 2020 20:58:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 14:39:18
User entered 'San Antonio'	System	23 Sep 2020 14:38:57

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:01:20
Reviewed for Safety.		05 Nov 2020 14:02:27
Un-reviewed for Safety.	System	14 Oct 2020 15:16:12
User entered empty.	System	14 Oct 2020 15:16:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:16:05
User entered 'Texas'	Victoria Hernandez (b) (4)	13 Oct 2020 20:46:47
	(b) (4)	

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 20:58:22
Reviewed for Safety.		23 Sep 2020 14:39:18
User entered '78229'	System	23 Sep 2020 14:38:57

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:05
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:58:22
User entered 'US'	System	23 Sep 2020 14:39:25

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:33:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '5'	(b) (4)	04 Jan 2021 14:52:38
User entered '4'	System	06 Nov 2020 13:14:38
User entered '3'	System	05 Nov 2020 14:02:37
User entered '2'	System	14 Oct 2020 15:16:12
User entered '1'	System	23 Sep 2020 14:39:25

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 16:33:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:47
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '04/Jan/2021 14:52'	(b) (4) System	04 Jan 2021 14:52:38

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:33:11

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:47
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 14:52:38



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'USA-US072-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'Douglas'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'Denham'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered '7940 Floyd Curl Drive'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'San Antonio'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered '78229'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 14:06:00
User entered 'US'	System	24 Nov 2020 13:55:07

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '3'	(b) (4) System	05 Jan 2021 16:24:15
User entered '2'	System	23 Dec 2020 14:06:10
User entered '1'	System	24 Nov 2020 13:55:07

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'USA-US072-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:54:38



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'Douglas'	System	24 Nov 2020 13:54:38



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'Denham'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered '7940 Floyd Curl Drive'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'San Antonio'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered '78229'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 14:06:00
User entered 'US'	System	24 Nov 2020 13:55:07

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '3'	(b) (4) System	05 Jan 2021 16:24:15
User entered '2'	System	23 Dec 2020 14:06:10
User entered '1'	System	24 Nov 2020 13:55:07

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:33:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '24/Nov/2020 13:55'	(b) (4) System	24 Nov 2020 13:55:07

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:33:11

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4)	23 Dec 2020 14:06:00
User entered 'l'	(b) (4), (b) (6)	24 Nov 2020 13:55:07



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'USA-US072-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'Douglas'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'Denham'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered '7940 Floyd Curl Drive'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'San Antonio'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered '78229'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 14:06:00
User entered 'US'	System	24 Nov 2020 13:55:07

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '3'	(b) (4) System	05 Jan 2021 16:24:15
User entered '2'	System	23 Dec 2020 14:06:10
User entered '1'	System	24 Nov 2020 13:55:07

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:33:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '23/Dec/2020 14:06'	(b) (4) System	23 Dec 2020 14:06:10



US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:33:11

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 16:24:00
User entered 'l'		23 Dec 2020 14:06:10

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'USA-US072-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'No (N)'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'Douglas'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'Denham'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered '7940 Floyd Curl Drive'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered 'San Antonio'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:54:58
User entered '78229'	System	24 Nov 2020 13:54:38

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 14:06:00
User entered 'US'	System	24 Nov 2020 13:55:07

**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:33:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '3'	(b) (4) System	05 Jan 2021 16:24:15
User entered '2'	System	23 Dec 2020 14:06:10
User entered '1'	System	24 Nov 2020 13:55:07



**US3292320**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:33:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered '05/Jan/2021 16:24'	(b) (4) System	05 Jan 2021 16:24:15

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:33:11

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:38:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:14:16
User entered 'I'	(b) (4), (b) (6)	05 Jan 2021 16:24:15